EPA Reg. No. 68451-1 Vol. 1



Application		REF. NO.	EVENT	DATE	RESPONS
8-11-93	165		Day dota Submitted u/3/3/3Colle	11-6-98	37
8-22-95	166	49 4860		5.2-96	16
8-21-95	166	1.494.967		5-2-96	16
5-13-96	166	506 323	Received Labelia per 5/2/96 ltr.	5-31-96	17
6-16-97	360	525902	Reised Lebelt re: PRN 96-6	10-17-97	17
alian dan berjada sa Marina dan merupakan	20	e distrib [®] in A We [®] transport with 12 \$50	And the set of the second of t	i de la companion de la compan La companion de la companion d	4
			ne The graph has a married as Language and a second	3 9 9	., .,
•					1
a some of	2011	, par a mar 14 mg 24	or kan a maja maja saka na naman na sa na na na na na		
				v	524
	X.	39 d d 5	do 8 199 2 7 2 4	9	. 0
			and the second of the second o		
200 200 200 200 200 200 200 200 200 200				terika di kacamatan	La Constant
Secretary and second second	E province			The state of the	
20 9 100 100 100 100 100 100 100 100 100					
				* 1	
					· · · · · · ·
	77				
			a a		
	77		N N	T	
	2(3/3)				1.0
					to:
					188 3 - 585



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

AUG 2 U 2003

Ms. Mary K. Hagler, MS Regulatory Specialist - Pharmaceuticals Intervet, Inc 405 State Street, P.O. Box 318 Millsboro, DE 19966

Subject:

Amendment - Revised First Aid Statements

Deltamethrin 4% Collar

EPA Registration No. 68451-1

Your Submission Dated May 20, 2003

Dear Ms. Hagler:

The amendment referred to above, submitted in connection with registration under section 3 (c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable, subject to the comments listed below.

Under the "Precautionary Statements" section, move the statements "Do not open...with this collar" and the paragraph beginning "Do not use on puppies under . . .etc" to the "Directions for Use" section of your label.

A stamped copy of the label is enclosed for your records. If you have any questions, please call Dr. William Sproat of my team at 703-308-8587.

Sincerely,

George T. LaRocca Product Manager 13 Insecticide Branch Registration Division (7505C)

Enclosure

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Kills Fleas and Ticks for up to 6 Months
LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (including deer ticks which may carry Lyme disease)
ALSO KILLS FLEAS

ACTIVE INGREDIENT: Deltamethrin

thrin

INERT INGREDIENTS Total Percentage by Weight 4.0%

96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar NET WT. 0.9 oz

Distributed by: Intervet Inc. 405 State Street Millsboro, DE 19966

Product of France



AUG 2 0 2003

Under the Federal Insecticide, Pungicide, and Rodenticlide Act, as amended, for the posticide registered under EPA Reg. No. 6845/-/

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR.

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Do not open protective pouch until ready to use. Do not let children play with this collar-

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING::	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF IN EYES:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the pr	For incidents involving HUMANS, call 1-800-680-9206 For incidents involving ANIMALS, call 1-800-548-2423 reduct container or label with you when calling a poison control center or doctor, or going for treatment.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened, INTERVET INC, warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC, MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESIS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC, be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

Intervet Inc. 405 State St; P.O. Box 318 Millsboro, DE 19966 Check if this is a new address Product Na Section - II Amendment - Explain below. Resubmission in response to Agency letter dated "Me"	3. Proposed Classification Restricted Restricted Restricted Restricted Restricted Red Reveiw. In accordance with FIFRA Section 3(c)(3) reduct is similar or identical in composition and labeling No.
4. Company/Product (Name) Deltamethrin 4% Collar 5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 405 State St; P.O. Box 318 Millsboro, DE 19966 Check if this is a new address Product Na Section - II Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.)	ed Reveilw. In accordance with FIFRA Section 3(c)(3) roduct is similar or identical in composition and labeling
Deltamethrin 4% Collar 5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 405 State St; P.O. Box 318 Millsboro, DE 19966 Check if this is a new address Product Na Section - II Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.)	ed Reveiw. In accordance with FIFRA Section 3(c)(3) roduct is similar or identical in composition and labeling
Intervet Inc. 405 State St; P.O. Box 318 Millsboro, DE 19966 Check if this is a new address Product Na Section - II Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. Check if this is a new address Product Na Section - II Final Agen Me The Check if this is a new address Product Na Section - II Final Agen Me The Check if this is a new address Check if this is a new address Product Na Section - II Final Agen Me The Check if this is a new address Resubmission in response to Agency letter dated Other Explanation: Use additional page(s) if necessary. (For section I and Section II.)	roduct is similar or identical in composition and labeling
Amendment - Explain below. Resubmission in response to Agency letter dated "Me ' Notification - Explain below Other Explanation: Use additional page(s) if necessary. (For section I and Section II.)	
Resubmission in response to Agency letter dated Agen "Me" Notification - Explain below Other Explanation: Use additional page(s) if necessary. (For section I and Section II.)	
	al printed labels in repsonse to ency letter dated a Too" Application. er - Explain below. emethrin 4% collar label as required by PR Notice 2001-6.
Section - III	
1. Material This Product Will Be Packaged In:	
	ging 2. Type of Container Metal Plastic Gless Paper ontainer Other (Specify)
3. Location of Net Contents Information 4. Size(s) Retail Container Label Container	5., Location of Label Directions
6. Manner in Which Lebel is Affixed to Product Lithograph Paper glued Stenciled	Other
Section - IV	
1. Contact Point (Complete items directly below for identification of individual to be contact	tected, if necessary, to process this application.)
Name Title Mary K. Hagler Regulatory Specialist -	- Pharmaceuticals Telephone No. (Include Area Code) (302) 934-4340
Certification I certify that the statements I have made on this form and all attachments thereto a I acknowledge that any knowlingly false or misleading statement may be punishable both under applicable law. 2. Signature 3. Title	6. Date Application

Mary K. Hagler

Regulatory Specialist - Pharmaceuticals

5. Date

2W-008



(302) 934-4340

20 May 2003

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Attn: George Larocca
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar EPA Reg. No. 68451-1

Dear Dr. Larocca,

In accordance with PR Notice 2001-6, enclosed is an amendment of the disposal instructions for the Deltamethrin 4% Collar label (EPA Registration # 68451-1) for your review and approval.

On 14 March 2003, Intervet Inc. submitted an amendment for the First Aid statements for the Deltamethrin 4% Collar label. This amendment is still under review at EPA. The enclosed label includes the proposed First Aid statements from the amendment submitted 14 March 2003 as well as the updated disposal statements.

A completed EPA Form 8570-1 is enclosed as well as a 3 copies of the draft label. The proposed changes to the label are highlighted in yellow on each of the 3 copies.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. (Hagler, MS

Regulatory Specialist - Pharmaceuticals

Intervet Inc.

Enclosure

Cintervet

Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966-0318

Tel. (302) 934-8051 FAX (302) 934-6087

PESTICIDE REGISTRATION ACTION TRACKING SYSTEM (PRAT) CODING FORM

IN PROCESSING INFO	RMATION			
Submission Bar Code: <u>S</u>	636181	ID Number: 68	8457-1	_Action Code: <u>3</u>
PM Team: 03 Review	wer: 10.5f	ROAT	Due Dat	e: 8 19 03
Date on Application:	512	0 / 03		
EPA Received Date:	5 12	1/03		
PM Received Date:	513	27/03		· ·
Chemical Code (1):		_ Chemical		*
Chemical Code (2):		_ Chemical		
Proposed Use: \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	18 prop	a Nobice		MP C
Description of Action:	**************************************			
Related Actions:		-		
OUT PROCESSING IN	FORMATIO	N		
Response Code:	R	esponse Date:		•
75-Day Response:	Yes	No	_ MOS: (1)	Cite All
CRP:	Yes	No	(4)	Not Applicable
Restricted Use	Yes	No		Not Applicable Selective
Exclusive Use:	Yes	No	_	
Manufacturing Use:	Yes	No	_	
Conditional Registration	: Data Requ	ired		
Guideline No	/a. /	_:	Due Date:	
Guideline No		_	Due Date _	

Comments:



(302) 934-4340

14 March 2003

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Attn: George Larocca
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar EPA Reg. No. 68451-1

Dear Dr. Larocca,

In accordance with PR Notice 2001-1, enclosed is an amendment of the First Aid statements for the Deltamethrin 4% Collar label (EPA Registration # 68451-1) for your review and approval.

A completed EPA Form 8570-1 is enclosed as well as a 5 copies of the draft label. The proposed changes to the label are highlighted in yellow on each of the 5 copies.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

May K. Hagler, MS

Regulatory Specialist – Pharmaceuticals

Intervet Inc.

Enclosure

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318
Tel. (302) 934-8051
FAX (302) 934-4292

5A	reverse before completing form.	Form A	paraved OMP No 207	0-0060, Approval expires 2-28-
\$EPA	United States Environmental Protecti Washington, DC 20	ion Agency	Registration Amendment Other	OPP Identifier Number
	Applicati	on for Pesticide - Se	ction I	
1. Company/Product Number 68451-1	or	2. EPA Product Me George Larocci		3. Proposed Classification None Restricted
4. Company/Product (Name Deltamethrin 4% Colla		PM#	03	
5. Name and Address of Ap Intervet Inc. 405 State St; P.O. Bo Millsboro, DE 19966	ox 318	(b)(i), my produc to:	t is similar or identical	with FIFRA Section 3(c)(3) in composition and labeling
	Here and the second	Section - II		
	nal page(s) if necessary. (For section is to revise the first aid statements	on I and Section II.)	plain below.	ice 2001-1.
# 1		Section - III		
1. Material This Product Wil	l Be Packaged In:	*****	1.0000000000000000000000000000000000000	
Child-Resistant Packaging Yes No * Certification must	Unit Packaging Yes No If "Yes" Unit Peckaging wgt. Vo. per container	Water Soluble Packaging Yes No If "Yes" Package wgt No. per	Pla GI Pa	tainer etal estic ess eper her (Specify)
3. Location of Net Contents	Information 4. Size(s) Recontainer	stail Container	5. Location of Label D	irections
6. Manner in Which Label is	f 1	graph Oth r glued ciled	er	
		Section - IV	-	
1. Contact Point (Complete	items directly below for identificati	on of individual to be contacted	, if necessary, to proces	s this application.)
Name Mary K. Hagler		Title Regulatory Specialist - Pha	CARLOS CARLOS CARLOS CONTRACTOR C	phone No. (frictude Area Code) 2) 934-4340
	Certific ments I have made on this form and y knowlingly false or misleading st	all attachments thereto are tro		6. Date Application Received (Stamped)

3. Title

5. Date

Regulatory Specialist - Pharmaceuticals

14 Mar 2003

2. Signeture

4. Typed Name

Mary K. Hagler

Please read Instructions on neverse	and the		Perm August	6 DUB No. 207		
SEPA Environment	United States al Protection hington, DC 20460	ion Agency		Registrati Amendm Other	Total Control of the	OPP Identifier Number 292637
12.00	Application	for Pesti	ide - Sectio	nl	# . "	
1. Company/Product Number			A Product Manage		3. Pro	oposed Classification
4. Company/Product (Name)		FMA	* 9**		14	None Restricted
Check if this is a new address	Codel	(b)(i), to: EPA				FIFRA Service 3(c)(3)
		Section			1	
Resubmission in response to Agency letter Notification - Explain below. Explanation: Use additional page(s) if necess	(and Section II	Other - Explain	- /-	2	
		Section -	101/			
1. Material This Product Will Be			1			
Child-Resistant Packaging Yes* No No If "Yes" Unit Packaging Western	No. per	Water Was No.	No. per container	48	ontainer Metal Plastic Glass Paper Other (S	,
Label Container	4. Statio files	Centerer		On Labelin		panying product
6. Manner in Which Label is Affixed to Product	Uthograp Reper gla Standard	nt's emid	Other _			
		Section -	IV			
1. Contact Point Complete Items directly	for identification of	of individual to	= contacted, if n	ecassary, to proc	ess this	application.)
Name	Tit	tle		Т	elephone	e No. (Include Area Code)
I certify that the statements I is made of acknowledge that any false of both under applicable law.		attachments				6. Date Application Received (Stamped)
2. Signature	3.	Title				
4. Typed Name	5.	Date				

11

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to everage 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and meinteining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other espect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2, Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for ell registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this posticide as it will appear on the label. The name must be specific to this product only.

 Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and eddress shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 5. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that partains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explenation of the purpose(s)
for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration
submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Salf-explanatory.
- 8. EPA Use Only.

				ber	
•	9	E	F	2/2	
1.	Çe	- P	any	/Fre	d

United States

Def Identifier Number

	55 55 55	Amendment 292637
A	pplication for Pesticide - Section I	
1, Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Company/Product (Name)	PM# O	NAMA Restricted
e, Name and Address of Applicant (Include ZIP Code) Check if this is a new address	(b)(i), my product is simil to: EPA Reg. No	n accordance with FIFRA Secretary 3(c)(3) ar or identical in composition and tabeling
The contract of	Section - II	
Amendment - Explain below. Resubmission in response to Agency letter de Notification - Explain below.	Final printed labels Agency letter date "Me Too" Applicate Other - Explain	on.
	Section - III	
1. Material This Product Will 8e Facility In:	- John Marie Control of the Control	
Child-Resistant Packaging Yes* No If "Yes"	No. per container	2. Type of Container Metal Plastic Glass Paper Other (Specify)
3. Lecurion of Net Conterna Information 4.	/E	On Label On Label On Label On Label On Label On Label On Labeling accompanying product
6. Manner in Which Label is Affixed to Product	Littragraph Papar glired Stansied	
	Section - IV	
1. Contact Point		
Name	Title	Telephone No. (Include Area Code)
	Certification his form and all attachments thereto are true, accus leading statement may be punishable by fine or im	
2. Signature	3. Title	
4. Typed Name	5. Date	* *

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20480.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). Ill not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only.

 Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product,
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Menner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

SEPA Environmental	Environmental Protection Agency Washington, DC 20460			Registrat Amendm Other	
	Application fo	r Pesticide - Se	ection	1	
1. Company/Product Number Intervet Inc./68451-1		2. EPA Product N George Larocc	_		3. Proposed Classification None Restricte
Company/Product (Name) Intervet Inc./ Deltamethrin 4% Collar	et ::===================================	PM#	4	5	
5. Name and Address of Applicant (Include ZIP Cod Intervet Inc. 405 State St.; P.O. Box 318 Millsboro, DE 19966 Check if this is a new address	de)	207.0	ct is sim	ilar or identic	ce with FIFRA Section 3(c)(3) cal in composition and labeling
	S	ection - II			n
Amendment - Explain below. Resubmission in response to Agency letter. Notification - Explain below. Explanation: Use additional page(s) if necessary. Label Revision: Revision of marketing claim per PR provisions of PR Notice 98-10 and EPA regulations a formula of this product. I understand that it is a violation of the provision of PR Notice 98-10 and EPA regulations at formula of this product. I understand that it is a violatinotification is not consistent with the terms of PR Notice procedure.	Notice 98-10 (see at at 40 CFR 152.46 , ar tion of 18 U.S.C. Sec ice 98-10 and 40 CF	Agency "Me Too Other - I I Section II.) tached draft label for product no other changes have a 1001 to willfully make	latter da b Applic Explain b oposed ch ve been n any false	etion. elow.	MAR 2 9 2002 Notification is consistent with the eling or the confidential statement of PA. I further understand that if this
	S	ection - III	1		
1. Material This Product Will Be Packaged In: Child-Resistant Packaging Yes No Certification must submitted 1. Material This Product Will Be Packaged In: Unit Packaging If "Yes" Unit Packaging wgt.	Wa No. per If "	ection - III eter Soluble Packaging Yes No Yes" No. p ckage wgt Conta	67	2. Type of C	Container Metal Plastic Glass Paper Other (Specify)
Child-Resistant Packaging Yes No No Certification must submitted 1 "Yes" Unit Packaging If "Yes" Unit Packaging wgt.	Wa No. per If "	iter Soluble Packaging Yes No Yes* No. p ckage wgt conta	er liner	2. Type of C	Metal Plastic Glass Paper Other (Specify)
Child-Resistant Packaging Yes No No Certification must submitted Unit Packaging Unit Packaging Ves No If "Yes" Unit Packaging wgt.	No. per container Par	ter Soluble Packaging Yes No Yes" No. p ckage wgt ntainer	er liner		Metal Plastic Glass Paper Other (Specify)
Child-Resistant Packaging Yes No No Certification must Submitted 1 Tyes" Unit Packaging wgt. 1 Tyes" Unit Packaging wgt.	No. per of the container of the containe	ter Soluble Packaging Yes No Yes" No. p ckage wgt ntainer	er iner 5. Lc		Metal Plastic Glass Paper Other (Specify)
Child-Resistant Packaging Yes No No Certification must submitted 15 "Yes" Unit Packaging No If "Yes" Unit Packaging wgt.	No. per container If Part Container Part Container Lithograph Paper glued Stenciled Se	ter Soluble Packaging Yes No Yes" No. p ckage wgt ntainer	5. Lo	ocation of Labo	Metal Plastic Glass Paper Other (Specify)
Child-Resistant Packaging Yes No Certification must submitted 3. Location of Net Contents Information Label Container 6. Manner in Which Label is Affixed to Product	No. per container If Pace A. Size(s) Retail Co Lithograph Paper glued Stenciled Second identification of in	ter Soluble Packaging Yes No Yes" No. p ckage wgt ntainer	5. Lo	cessary, to pro	Metal Plastic Glass Paper Other (Specify)
Child-Resistant Packaging Yes No No If "Yes" Unit Packaging wgt. **Submitted* 3. Location of Net Contents Information Label Container 6. Manner in Which Label is Affixed to Product 1. Contact Point (Complete items directly below for Name	No. per container If Container Par Container Paper glued Stenciled Title Regular Cortification of in Container Certification this form and all attention and all attentions the container	ter Soluble Packaging Yes No Yes No. p ckage wgt contact Intainer Caction - IV Individual to be contact Ulatory Specialist - Ph	5. Lo	essary, to prouticals	Metal Plastic Glass Paper Other (Specify) Directions cess this application.) Telephone No: (Include Area Code (302) 934-4340 6. Date Application
Child-Resistant Packaging Yes No No Certification must Submitted 3. Location of Net Contents Information Label Container 6. Manner in Which Label is Affixed to Product 1. Contact Point (Complete items directly below for Name Mary K. Hagler I certify that the statements I have made on I acknowledge that any knowlingly false or it.	No. per container If Pace Container Paper glued Stenciled Title Regulation this form and all attention statements of the contained statement of the containe	No Yes No	ther	essary, to prouticals	Metal Plastic Glass Paper Other (Specify) Directions cess this application.) Telephone No. (Include Area Code (302) 934-4340 6. Date Application. Regeived

Paperwork Reduction Act Notice and Instructions

<u>Paperwork Reduction Act Notice</u>: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

<u>Instructions</u>: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- Five copies of draft labeling;
- Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific Instructions: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from the party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3(c) 3(b) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar, or identical to other pesticide products that are currently registered with the EPA. In order for you application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

Section II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by . . . "; "reregistration submission"; "general label revision of use directions." Attach a separate page is additional space is needed.

Section III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual
 Packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. ••• Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product,
- 5. ••• Location of the Use Directions Indicate the location of the use directions for your product.
- 6. . . Manner in which label is affixed to product Indicated the method product label is attached to retail container.

Section IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-teo," registration, etc.

- 1-5. Self-explanatory
- 6. EPA Use only

NOTIFICATION MAR 2 9 2002

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

→ Kills Fleas and Ticks for up to 6 Months ←
LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (including deer ticks which may carry Lyme disease)
ALSO KILLS FLEAS

ACTIVE INGREDIENT:

Deltamethrin

INERT INGREDIENTS Total Percentage by Weight

4.0%

96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar NET WT, 0.9 oz

Distributed by: Intervet Inc. 405 State Street Millsboro, DE 19966

Product of France



READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO RUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4%Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

fage 2 of 2 21 march 2000



(302) 934-4340

21 March 2002

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the Deltamethrin 4% Collar label (EPA Registration #: 68451-1; Intervet Inc., Company #: 54382). The label was previously approved per EPA letter dated 17 November 1998 and modified via notification dated 21 Dec 2001.

 The following text, consistent with statements on page 2 of the label, is being added to page 1 of the label:

Kills Fleas and Tick for up to 6 months

2. The following statement is being added to page 1 of the label:

See Back for additional Precautionary Statements

2. The following statement is being added to page 2 of the label:

Collar also kills ticks for up to 6 months.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed changes of the label are underlined, highlighted and bracketed with arrows (→←). In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely.

Mary K. Hagler, MS

Regulatory Specialist – Pharmaceuticals

Intervet Inc.

Enclosure

Cintervet

Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966-0318 Tel. (302) 934-8051 FAX (302) 934-6292

The read Instructions on		United States	7		Registr	ation	OPP Identifier Number	
\$EPA	Environmental Protection A Washington, DC 20460					ment		
		Application	on for Pesticid	e - Section	-			
I. Company/Product Numb			and the state of	roduct Manager		3. Pr	oposed Classification	
Intervet Inc./68451-1			George Larocca				None Restricted	
 Company/Product (Nam Intervet Inc./ Deltame 	e) thrin 4% Collar		PM#					
5. Name and Address of A	pplicant (Include ZIP Co	ode)	6. Expe	dited Reveiw	. In accord	ance with	FIFRA Section 3(c)(3)	
Intervet Inc.			100	y product is si	milar or iden	tical in co	mposition and labeling	
405 State St.; P.O.		-	to:	eg. No.	. dr			
Millsboro, DE 1996		- 10			4	9	3	
Check if ti	is is a new address		Produc	t Name				
			Section - II					
Amendment - Expl	sin below.	±50		Final printed lab		se to		
Resubmission in re	sponse to Agency lette	r dated		"Me Too" Appl			7	
				Other - Explain		(4)	- "	
Notification - Exple	in below.	×						
formula of this product. I unotification is not consister	inderstand that it is a viol it with the terms of PR N	lation of 18 U.S. otice 98-10 and	.C. Sec. 1001 to willful 40 CFR 152.46, this p	lly make any fals	e statement to	EPA. I fur	her understand that if this	
formula of this product. I u	inderstand that it is a viol it with the terms of PR N	lation of 18 U.S. otice 98-10 and	.C. Sec. 1001 to willful 40 CFR 152.46, this p	lly make any fals product may be i	e statement to	EPA. I fur	her understand that if this	
formula of this product, I unotification is not consister enforcement action and performent action action action action action action.	Inderstand that it is a viol it with the terms of PR No inalties under sections 12 Will Be Packaged In:	lation of 18 U.S. otice 98-10 and	.C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III	ily make any fals product may be i	e statement to n violation of f	EPA. I fur FIFRA and I	her understand that if this may be subject to	
formula of this product. I unotification is not consister enforcement action and performent action and performent action and performent action. 1. Material This Product V. Child-Resistant Packaging	nderstand that it is a viol at with the terms of PR No malties under sections 12 Vill Be Packaged In: Unit Packaging	lation of 18 U.S. otice 98-10 and	.C. Sec. 1001 to willful 140 CFR 152.46, this p RA.	ily make any fals product may be i	e statement to n violation of f	EPA. I fun IFRA and I	her understand that if this may be subject to	
formula of this product. I condification is not consister enforcement action and performed the product of the p	vill Be Packaged In: Unit Packaging Yes	lation of 18 U.S. otice 98-10 and	.C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III	ily make any fals product may be i	e statement to n violation of f	EPA. I fur IFRA and I	her understand that if this may be subject to	
formula of this product, I condification is not consister enforcement action and performent action. 1. Material This Product V. Child-Resistant Packaging	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No	lation of 18 U.S. otice 98-10 and 2 and 14 of FIFF	C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III Water Soluble Pa Yes No	ily make any fals product may be i	e statement to n violation of f	FPA. I fur FRA and I f Contained Metal Plastic Gless	her understand that if this may be subject to	
formula of this product. I condification is not consister enforcement action and performent action action. 1. Material This Product V. Child-Resistant Packaging	vill Be Packaged In: Unit Packaging Yes	lation of 18 U.S. otice 98-10 and 2 and 14 of FIFF	C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III Water Soluble Pa	ily make any fals product may be i	e statement to n violation of f	FPA. I fun IFRA and I If Contained Metal Plastic Gless Paper	her understand that if this may be subject to	
formula of this product. I unotification is not consister enforcement action and performed the product of the p	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wg	No. per t. container	C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III Water Soluble Pa Yes No If "Yes"	lly make any fals product may be i sckeging No. per container	e statement to n violation of f	FPA. I fur IFRA and I If Contained Metal Plastic Glass Paper Other (may be subject to	
formula of this product. I contification is not consister enforcement action and performed action action. It is a submitted action of Net Contents of Net Contents action of Net Contents action of Net Contents.	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wgt Information Container	No. per t. container 4. Size(s) Re	C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III Water Soluble Pa Yes No If "Yes" Package wgt	lly make any fals product may be i sckeging No. per container	2. Type o	FPA. I fur IFRA and I If Contained Metal Plastic Glass Paper Other (ther understand that if this may be subject to	
formula of this product. It is notification is not consister enforcement action and performed action	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wgt Information Container	No. per t. container 4. Size(s) Re	C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III Water Soluble Pa Yes No If "Yes" Package wgt stell Container graph r glued cifed	No. per container	2. Type o	FPA. I fur IFRA and I If Contained Metal Plastic Glass Paper Other (ther understand that if this may be subject to	
formula of this product. It is notification is not consister enforcement action and performed action	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wgf ts Information Container Is Affixed to Product	No. per t. container 4. Size(s) Re Lithor	C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III Water Soluble Pa Yea No If "Yes" Package wgt stell Container graph r glued ciled Section - IV	No. per container Other	2. Type c	FPA. I fur IFRA and I Metal Plastic Gless Paper Other (her understand that if this may be subject to Specify)	
formula of this product. It is notification is not consister enforcement action and performed action	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wgf ts Information Container Is Affixed to Product	No. per t. container 4. Size(s) Re Lithor	C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III Water Soluble Pa Yea No If "Yes" Package wgt stell Container graph r glued ciled Section - IV	No. per container Other	2. Type c	FPA. I fur IFRA and I If Containe Metal Plastic Glass Paper Other (ther understand that if this may be subject to Specify) ons	
formula of this product. It notification is not consister enforcement action and performed action ac	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wgf ts Information Container Is Affixed to Product	No. per t. container 4. Size(s) Re Lithor	C. Sec. 1001 to willful 40 CFR 152.46, this p RA. Section - III Water Soluble Pa Yes No If "Yes" Package wgt otell Container graph r glued cided Section - IV fon of individual to be	No. per contacted, if n	2. Type of Location of L	FPA. I fur IFRA and I If Containe Metal Plastic Glass Paper Other (her understand that if this may be subject to Specify) ons s application.	
formula of this product. It is notification is not consister enforcement action and performed action	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wgf The Affixed to Product Stellars directly below Interments I have made of any knowlingly false of any knowlingly false of any knowlingly false of any knowlingly false of the items of the it	No. per t. Container 4. Size(s) Re Certific on this form an	C. Sec. 1001 to willful 40 CFR 152.46, this p RA. Section - III Water Soluble Pa Yea No If "Yes" Package wgt stell Container graph r glued ciled Section - IV fon of Individual to be Title Regulatory Specia	No. per contacted, if n	2. Type of Location of Locatio	FPA. I fur IFRA and I If Contained Metal Plastic Gless Paper Other (abel Directi Telephor (302) 93	her understand that if this may be subject to Specify) ons s application.	
formula of this product. It is notification is not consister enforcement action and performed action action and performed action action and performed action action action and performed action	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wgf The Affixed to Product Stellars directly below Interments I have made of any knowlingly false of any knowlingly false of any knowlingly false of any knowlingly false of the items of the it	No. per t. Container 4. Size(s) Re Certific on this form an	C. Sec. 1001 to willful 40 CFR 152.46, this p RA. Section - III Water Soluble Pa Yea No If "Yes" Package wgt stell Container graph r glued ciled Section - IV fon of Individual to be Title Regulatory Specia	No. per contacted, if n	2. Type of Location of Locatio	FPA. I fur IFRA and I If Contained Metal Plastic Gless Paper Other (abel Directi Telephor (302) 93	Specify) s application.) ne No. (Include Area Code 4-4340 8. Date Application Received	
formula of this product. It is notification is not consister enforcement action and performed action	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wgf The Affixed to Product Stellars directly below Interments I have made of any knowlingly false of any knowlingly false of any knowlingly false of any knowlingly false of the items of the it	No. per t. Container 4. Size(s) Re Certific on this form an	C. Sec. 1001 to willful 140 CFR 152.46, this p RA. Section - III Water Soluble Pa Yes No If "Yes" Package wgt Section - IV or of Individual to be Title Regulatory Speciation d all attachments the tatement may be pun	No. per container Other	2. Type of Location of Locatio	FPA. I fur IFRA and I If Contained Metal Plastic Gless Paper Other (abel Directi Telephor (302) 93	Specify) s application.) ne No. (Include Area Code 4-4340 8. Date Application Received	
formula of this product. It is notification is not consister enforcement action and performed action	with the terms of PR Normalities under sections 12 Will Be Packaged In: Unit Packaging Yes No If "Yes" Unit Packaging wgf The Affixed to Product Stellars directly below Interments I have made of any knowlingly false of any knowlingly false of any knowlingly false of any knowlingly false of the items of the it	No. per t. Container 4. Size(s) Re Certific on this form an	C. Sec. 1001 to willful 40 CFR 152.46, this p RA. Section - III Water Soluble Pa Yea No If "Yea" Package wgt Section - IV fon of individual to be Title Regulatory Special attement may be pun 3. Title	No. per container Other	2. Type of Location of Locatio	FPA. I fur IFRA and I If Contained Metal Plastic Gless Paper Other (abel Directi Telephor (302) 93	Specify) s application.) No No. (Include Area Code 4-4340 8. Date Application Received	

Hese read instructions on	reverse before comple	eting form.	Form A	pprove			OPP Identifier Number
\$EPA	United States Environmental Protection Agency Weshington, DC 20480			~	Registra Amenda Other		OPP Identifier Number
		Applicati	on for Pesticide - Se	ction	1		1
1. Company/Product Number	or	1111-22	2. EPA Product M			3. P	roposed Classification
Intervet Inc./68451-1 4. Company/Product (Name		_	George Larocc	a		\dashv \Box	None Restricted
Intervet Inc./ Deltamet			rms				
5. Name and Address of Ap Intervet Inc. 405 State St.; P.O. B Millsboro, DE 19966	lox 318	odej		t is sin	nilar or iden		FIFRA Section 3(c)(3) emposition and labeling
			Section - II				
Notification - Explain Explanation: Use addition Label Revision: Revision of provisions of PR Notice 98- formula of this product. I un	ponse to Agency letter helow. mail page(s) if necessar marketing claim per Pi 10 and EPA regulations derstand that it is a vio with the terms of PR N	ry. (For section R Notice 98-10 at 40 CFR 15: lation of 18 U.S lotice 98-10 and	Agency I "Me Too Other - E on I and Section II.) (see attached draft label for pro 2.46 , and no other changes hav 5.C. Sec. 1001 to willfully make a d 40 CFR 152.46, this product m	Application by the posed of the period of th	hanges). This	notificatio	ne confidential statement of ther understand that if this
		-	Section - III	-			
1. Material This Product W	ill Se Packaged In:						
Child-Resistent Packaging Yes No Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wg	No. per t. container	Weter Soluble Packaging Yes No If "Yes" No. per Package wgt contain		2. Type of	Metal Plastic Glass Paper	Specify)
3. Location of Net Contents	Information Container	4. Size(s) R	atail Container	5. L	ocation of La	bel Directi	ons
6. Manner in Which Label is		Litho	ograph Or or glued ciled	ther _			•—
			Section - IV				
The state of the s	e items directly below	for identificat	ion of individual to be contact	ed, if ne	cessary, to p		
Name Mary K. Hagler			Title Regulatory Specialist - Ph	amace	outicals	(302) 93	ne No. (Include Area Code 4-4340
	ny knowlingily false o		ation d all attachments thereto are tatement may be punishable b				6. Date Application Received (Stamped)
2. Signature Mary K.	tagle		3. Title Regulatory Specialist - Pharm	naceutic	als		
4. Typed Name Mary K. Hagler	0		5. Date 21 March	201	02		

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

→ Kills Fleas and Ticks for up to 6 Months ← LONG LASTING PROTECTION FOR UP TO 6 MONTHS Kills Ticks (including deer ticks which may carry Lyme disease) ALSO KILLS FLEAS

ACTIVE INGREDIENT:

Percentage by Weight

4.0%

Deltamethrin

96.0%

INERT INGREDIENTS

Total

100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar NET WT. 0.9 oz

Distributed by: Intervet Inc. 405 State Street Millsboro, DE 19966

Product of France

Page 1 of 2 21 March 2002

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4%Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNE'SS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC, be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

Page 2 of 2 21 march 2302



(302) 934-4340

21 March 2002

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the Deltamethrin 4% Collar label (EPA Registration #: 68451-1; Intervet Inc., Company #: 54382). The label was previously approved per EPA letter dated 17 November 1998 and modified via notification dated 21 Dec 2001.

1. The following text, consistent with statements on page 2 of the label, is being added to page 1 of the label:

Kills Fleas and Tick for up to 6 months

2. The following statement is being added to page 1 of the label:

See Back for additional Precautionary Statements

2. The following statement is being added to page 2 of the label:

Collar also kills ticks for up to 6 months.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed changes of the label are underlined, highlighted and bracketed with arrows (→←). In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler, MS

Regulatory Specialist – Pharmaceuticals

Intervet Inc.

Enclosure

Cintervet

Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966-0318

Millsboro, DE 19966-0318 Tel. (302) 934-8051 FAX (302) 934-4292

MAY-14-2002 08:47 VIRBAC CORP. 8178312878 Please Read All Instructions Before Completing this Form (Form must be typed) Form Approved, OMB No. 2070-0044. Approval Expires 1-31-96 United States Environmental Protection Agency 285€47 Office of Pesticide Programs (H7505C) 401 M Street SW Washington, DC 20460 Notice of Supplemental Distribution of a Registered Pesticide Product Instructions After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown. If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency. This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor. Distributor Company Number **EPA Registration Number of Product** 68451-1 8 2382 Note: Do not submit distributor product labels Name of Registered Product (basic product name accepted by EPA) Distributor Product Name Deltamethrin 4% Collar Preventef-D Flea & Tick Collar for Dogs Name and Address of Distributor (Type; include ZIP code) Virbac AH, Inc. PO Box 162059 Fort Worth, TX 76161 Read All Conditions Before Signing The distributor product must have the same composition as the basic product. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product. 3. The labeling for the distributor product must bear the same claims as the basic product, provided, however that specific claims may be deleted if by doing so, no other changes to the label are necessary. 4. The product must remain in the manufacturer's unbroken container. 5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number. 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for ...," distributed by..."; or sold by..." to show that the name is not that of the manufacturer. 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product. Distributor We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice. Signature and Title of Distributor michelle foxus. Registration Specialist 5114 100

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

16 May 2002

EPA Form 8570-5 (Rev. 2-92) Previous editions are obsolete

United States Environmental Protection Agency Office of Pesticide Programs (H7505C)

401 M Street SW Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the Distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

4 68451-1 8

Distributor Company Number

4758

Note: Do not submit distributor product labels

Name of Registered Product

(basic product name accepted by EPA)

Distributor Product Name

Deltamethrin 4% Collar

Adams Delta Force Tick Collar for Dogs

Name and Address of Distributor

(Type; include ZIP code)

Pet Chemicals P.O. Box 18993 Memphis, TN 38181

Read All Conditions Before Signing

- 1. The distributor product must have the same composition as the basic product.
- 2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered product.
 - The labelling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
- 4. The product must remain in the manufacturer's unbroken container.
- 5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
- 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for..", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
- 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Date

Bill Washburn, Product Development & Regulatory Affairs Manager

9/28/01

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

S. Lee Whaley, Manager, Regulatory Affairs - Pharmaceuticals

EPA Form 8570-5 (Rev.2.92)

Previous editions are obsolete.

John Son Jo Silv miles.

Telefax Transmittal Cover sheet



Page 1 of 7 Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966 (302) 934-8051

February 14, 2002

pages including cover sheet.

COMPANY/DEPT TO: **FAX NUMBER:** PERSON TO:

Mrs. Linda Arrington

U.S. Environmental Protection Agency

703-305-6920

FAX NUMBER: PERSON FROM: COMPANY/DEPT FROM:

S. Lee Whaley, MS

Intervet Inc..

Fax: 302-934-4209

Manager, Regulatory Affairs -**Pharmaceuticals**

Regulatory Affairs

Phone: 302-934-4385

RE: Deltamethrin 4% Collar – EPA Registration #68451-1 (Notification Submitted 21 Dec 2001)

Dear Mrs. Arrington:

As we discussed today, please find attached two EPA letters (both dated 14 March 2001) regarding the change of name and ownership of company numbers 68451 and 54382 from Hoechst Roussel Vet to Intervet Inc. Both company numbers now refer to:

intervet Inc. 405 State Street, P.O. Box 318 Millsboro, DE 19966-0318.

As we discussed, Intervet Inc. is the primary registrant of Deltamethrin 4% Collar (EPA Registration #68451-1) and, as such, Item 1 of the Form 8570-1 Notification submitted 21 December 2001 should have referenced "68451-1" instead of "54382/68451-1". I apologize for any confusion this may have caused. Thank you once again for the notification acknowledgement sent on 14 January 2002. Please feel free to contact me should you have any further questions.

Sincerely.

S. Lee Whaley, MS

Manager, Regulatory Affairs - Pharmaceuticals

Intervet Inc.

(Intervel)

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED, AND MAY CONTAIN PROPRIETARY INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF YOU ARE NOT THE ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, NOTIFY US IMMEDIATELY BY TELEPHONE (COLLECT). THANK YOU.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Page 2 of 7

March 14, 2001

Mr. Bryan Gathagan Vice President, Information & Control Invervet, Inc. 405 State Street, PO Box 318 Hillsboro, DE 19966-0318

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dear Mr. Gathagan:

Subject: Change of Name and Ownership of Company Number 68451

Pursuant to your letter and agreement of February 7, 2001, we have approved the change in name and ownership of Hoechst-Roussel Vet, company number 68451.

Our records are being amended to show the registrant and Agent under company number 68451 as follows:

Intervet, Inc. 405 State Street; PO Box 318 Millsboro, DE 19966-0318

Authorized Representative:

Bryan Gathagan (302) 934-8051

The effective date of this change is the date of this letter.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

 (\cdot)

Page 3 of 7

3029344209

2

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Page 4 of ?

3

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Donna G. Parker

Information Management Specialist

Information Services Branch

Information Resources & Services Div. (7504C)

CC: Mr. Brett Whitehead
 Vice President of Animal Health Business Unit
 Hoechst-Roussel Vet
 Perryville Corporate Park; PO Box 4010
 Clinton, NJ 08809-4010



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Page 5 of 7

3029344209

March 14, 2001

Mr. Bryan Gathagan
Vice President, Information &
Control
Invervet, Inc.
405 State Street, PO Box 318
Hillsboro, DE 19966-0318

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dear Mr. Gathagan:

Subject: Change of Name and Ownership of Company Number 54382

Pursuant to your letter and agreement of February 7, 2001, we have approved the change in name and ownership of Hoechst-Roussel Vet, company number 54382.

Our records are being amended to show the registrant and Agent under company number 54382 as follows:

Intervet, Inc. 405 State Street; PO Box 318 Millsboro, DE 19966-0318

Authorized Representative:

Bryan Gathagan (302) 934-8051

The effective date of this change is the date of this letter.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Page 6 of 7

2

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above:

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA. ()

()

Page 7.f7

3

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Donna G. Parker

Information Management Specialist

. S. Parla

Information Services Branch

Information Resources & Services Div. (7504C)

cc: Mr. Brett Whitehead
Vice President of Animal Health Business Unit
Hoechst-Roussel Vet
Perryville Corporate Park; PO Box 4010
Clinton, NJ 08809-4010

SEPA	United States Environmental Protection Agency Washington, DC 20460				~	Registr Amend Other		OPP Identifier Number
		Application	on for Pestic	de - Sec	tion	1		
1. Company/Product Number			1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2. EPA Product Manager George Larocca			3. Proposed Classification	
 Company/Product (Name Intervet Inc./ Deltamet) 			PM#					
5. Name and Address of Ap Intervet Inc. 405 State St.; P.O. B Millsboro, DE 19966	ox 318	ode)	(b)(i), r to: EPA					n FIFRA Section 3(c)(3) composition and labeling
			Section -	li .			AU	OTIFICATION
Resubmission in responsion in	below. nal page(s) if necessa s to the label front pane 98-10 and EPA regulati understand that it is a v with the terms of PR No	ry. (For sectional, per PR Notice ons at 40 CFR iolation of 18 Uptice 98-10 and	e 98-10 (see attache 152,46, and no othe .S.C. Sec. 1001 to w 40 CFR 152,46, this	Agency lett "Me Too" / Other - Exp ed draft label for changes ha rillfully make a	ter dat Applic Iain be	ation. slow. posed changen made to the se statement	es). This note labeling to EPA. It	or the confidential statement further understand that if this
			Section - I	11				
1. Material This Product Wil	Be Packaged In:							
Child-Resistant Packaging Yes No Certification must Submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt	No. per . container	Water Soluble F Yes No If "Yes" Package wgt	No. per			Metal Plastic Glass Paper Other (S	Specify)
3. Location of Net Contents	Information Container	4. Size(s) Re	tail Container		5, Lo	cation of La	bel Directi	ons
6. Manner in Which Label is	Affixed to Product	Lithog Paper Stenc	reph glued iled	Othe				
			Section - I	V				
1. Contact Point (Complete	items directly below	for identification	on of individual to b	e contacted,	if nec	essary, to p	rocess this	s application.)
Name S. Lee Whaley			Title Manager, Regula	atory Affairs	- F'ha	rma	Telephon (302) 934	ne No. (Include Area Code) 4-4385
I certify that the state I acknowledge that an both under applicable	y knowlinglly false or	misleading sta	all attachments thatement may be pur		The second		The second secon	6. Date Application Received (Gtamped)
2. Signature			3. Title					

4. Typed Name

S. Lee Whaley

Manager, Regulatory Affairs - Pharmaceuticals

21 December 2001

5. Date

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

ACCEPTED
with COMMENTS
in EPA Letter Dated

NOV 17 1998

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

ACTIVE INGREDIENT:

Deltamethrin

Percentage by Weight 4.0%

INERT INGREDIENTS

Total

96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

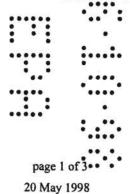
See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 1.1 oz



Hoechst Roussel Vet SA 102 route de Noisy 93235 Romainville, France

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterianarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide- release technology. Maximum effectiveness may not occur for 2—3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes sp.) which may carry the Lyme disease. Collar kills and repels mosquitoes (Aedes aegypti) and prevents them from feeding. This collar should be worn continuously. Reapply a new collar every 6 months:

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle-and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of net must also be treated with appropriate pest control measures to ensure control of pests. We ting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

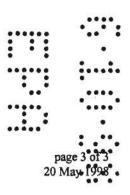
Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET S.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

The Hoechst Name and logo are registered trademarks of Hoechst AG.

© 1998 HRV S.A.

Part No. XXXXX

Universal Product Code Number (Bar Code)

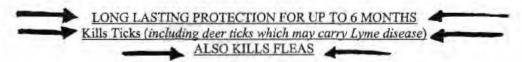


NOTIFICATION

JAN 1 4 2002

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS



ACTIVE INGREDIENT:

Deltamethrin

Percentage by Weight

4.0%

INERT INGREDIENTS Total

96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar NET WT. 0.9 oz

Distributed by: Intervet Inc. 405 State Street Millsboro, DE 19966

Product of France

Page 1 of 2 21 Dec 2001

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4%Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

Page 20f2 21 Dec 2001



21 December 2001

Document Processing Desk (NOTIF) Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202-4501

CATION JAN 1 4 2002

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the Deltamethrin 4% Collar label (EPA Registration #: 68451-1; Intervet Inc., Gempany #: 54382). The label was previously approved per EPA letter dated 17 November 1998.

1. The following text, consistent with statements on page 2 of the label, are being added to page 1 of the label:

> LONG LASTING PROTECTION FOR UP TO 6 MONTHS Kills Ticks (including deer ticks which may carry Lyme disease) ALSO KILLS FLEAS

The following statement is being added to page 1 of the label:

Adjustable – One Size Fits All

3. The statement, "See Side Panel for additional Precautionary Statements" is revised to read:

"See Insert or Side Panel for additional Precautionary Statements"

Note also that the net wt. is being revised from 1.1 oz. to 0.9 oz. to better reflect the weight of the collar.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed changes to page 1 of the label are underlined, highlighted and bracketed with arrows (→←). Note that there are no changes to page 2 of the label. In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4385) or e-mail (lee.whaley@intervet.com) should you have any questions.

Sincerely,

S. Lee Whaley, MS

Manager, Regulatory Affairs - Pharmaceuticals

Intervet Inc.

Enclosure



405 State Street P.O. Box 318 Millsboro, DE 19966-0318 Tel. (302) 934-8051



United States

Environmental Protection Age

Office of Pesticide Programs (7505C) Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

EPA Reg. No. 1 68451-1 8

Distributor Company Number

54382

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

Deltamethrin 4% Collar

Distributor Product Name

Deltamethrin 4% Collar

ame and Address of Distributor (Type; include ZIP code)

Hoechst Roussel Vet 30 Independence Blvd., Box 4915 Warren, NJ 07059

Read All Conditions Before Signing

- 1. The distributor product must have the same composition as the basic product.
- 2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
- 3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
- The product must remain in the manufacturer's unbroken container.
- 5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
- 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
- 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on Mis Notice.

Signature and Title of Distributor

Jane Kingett, Registration Specialist

Oct 1998

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant Agent for Hoechst Roussel Vet S.A. John J. Lauber, Manager, Product Reg. Date 9.0ct 1998

United States

Environmental Protection Agency

Office of Pesticide Programs (7505C)

Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the

distributor apply, on letterhead stationery, to the Registra this form to the agency.	ation Division to have a number assigned prior to submitting
This Notice of Supplemental Distribution must be submitt the concurrence and signature of both the registrant and	ted by the basic registrant. The completed form must have the distributor.
EPA Registration Number of Product	Distributor Company Number
4 68451-18	3 2781
Note: Do not subm	it distributor product labels
Name of Registered Product (basic product name accepted by EPA) DELTAHETHRIN 4% COLLAR	Distributor Product Mappe HAPPY JACK NOVATION THE FLER & TICK COLLAR FOR DOGS
Name and Address of Distributor (Type; include ZIP code)	
P.O. Box C HICHWAY SNOW H	475 4 258 SOUTH
	CAROUNA 28580
Read All Conditions	Before Signing
The distributor product must have the same composit The distributor product must be manufactured and pa the registered basic product.	ion as the basic product. ckaged by the same person who manufactures and package
The labeling for the distributor product must bear the specific claims may be deleted if by doing so, no other	
The product must remain in the manufacturer's unbro 5. The label must bear the EPA registration number of the company number.	ken container. ne basic product, followed by a hyphen and the distributor's
Distributor product labels must bear the name and add for", "distributed by"; or "sold by" to show that	
B II NO. 10 THE SECOND	o distributor products. It is the responsibility of the basic compliance with requirements placed on the basic product.

Distributor

We interfet to nearket our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice,

Registrant

distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this agree that the Notice.

Regulatory Specialist

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete.

Paperwork Reduction Act Notice

The annual respondent burden for the Notice of Supplemental Distribution of a Registered Pesticide Product is estimated to average 15 minutes per response, including time for reviewing the instructions, searching existing at a sources, gathering and maintaining the datameteded, and completing and reviewing the information. Send comments regarding this burden, to Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington; DC 20460; and to Paperwork Reduction Project (OMB No. 2070-0044), Office of Management and Budget, Washington, DC 20503, Marked "Attention Desk Officer for EPA."

71 120

Gane seine - Tomatany recia

NOV 17 1998

John J. Lauber Hoechst Roussel Vet Agent for Hoechst Roussel Vet S.A. 30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Subject:

Deltamethrin 4% Collar

EPA Registration No. 68451-1 Amendment dated June 4, 1998

Dear Mr. Lauber:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you:

- Make the following changes to your label:
- a. Based on the submitted studies, the addition of the claims for "deer ticks" is acceptable. Black-legged ticks is also acceptable. However, if a species name specific claim is made, then only Ixodes scapularis and/or Ixodes pacificus may be used in addition to the terms above. Ixodes sp. is not acceptable, and should be removed from the label and the above species names should replace it.
- b. The label claim for mosquitoes reads: "Collar kills and repels mosquitoes and prevents them from feeding." The data submitted do not support these claims and for the following reasons they should be removed from the label:
- 1) The data do not show that this product is an efficacious repellent. The study results demonstrate a reduction in blood-feeding but this reduction is insufficient to support repellent claims. The maximum reduction in feeding between the control and treated groups is 84.4% with a range of 15.9% to 84.4%. In addition, there was no statistically significant difference in landings between treated and control groups.

The data do not support the "kill" claim for mosquitoes. The range was 69% -91.1%. The 91.1% mortality result was for one data point only. All other

EDA Form	- 1200 1A (100)			District			OFFICE	A FILE COPY
DATE								
SURNAME								
SYMBOL	Subdivision	G Guideline	es.					
	THE RESERVE AND ADDRESS OF THE PARTY.	Name and Address of the Owner, where the Parket of the Owner, where the Parket of the Owner, where the Owner,	THE RESERVE TO SHARE THE PARTY OF THE PARTY	EIOMOMUNREN	dals is less th	ian the 95%	required by	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

-2-

Submit two copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records. I have also enclosed copies of the reviews for your records. If you have any questions about this letter, please contact Beth Edwards at (703) 305-5400.

Sincerely yours,

Beth Edwards

George T. LaRocca Product Manager 13 Insecticide Branch

Registration Division (7505C)

Enclosures

	V-0 2			CONCURRENC	ZES			
SYMBOL	N	Y			1000			
SURNAME	X		***************	**************	*************	***************************************	************	
DATE	X		****************	*************			***************************************	
EPA Form	n 1320-1A (1/90)			Printed on Recycles	i Paper		OFFICE	ALL BILE COPY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

21 /OCTOBER/1998

MEMORANDUM

Subject:

EPA Reg. No.: 68451-00001 Deltamethrin 4% Flea Collar

DP Barcode: D248074 Case No: 034680

From:

Eugenia McAndrew, Biologist

Technical Review Branch

Registration Division (7505C)

To:

Beth Edwards, PM Team 03

Insecticide Branch

Registration Division (7505C)

Applicant:

Hoechst Roussel Vet

30 Independence Blvd.

P.O. Box 4915 Warren, NJ 07059

FORMULATION FROM LABEL:

Active Ingredient(s):

097805 Deltamethrin

% by wt.

4.0

Inert Ingredient(s):

96.0

Total:

100.%

ACTION REQUESTED: "Please review information submitted to support the revision of the First Aid Statement for the subject product to delete "induce vomiting."

BACKGROUND: The Registrant has submitted a letter proposing to revise the label concerning first aid statements for EPA Reg. No. 68451-00001 Deltamethrin 4% Collar. The revision would delete the instruction to "induce vomiting." The letter states as follows:

"Since ingestion of even an entire flea collar does not appear to cause much of an acute toxicity hazard, except perhaps in very small children (and animals), it is our opinion that vomiting should not be induced as first aid treatment following collar ingestion due to the potential danger of aspiration (or other physical trauma) of the foreign material particularly if the collar has been bitten or chewed into smaller segments.

In certain circumstances, particularly with ingestions by small children (and animals) for example, it may be necessary to retrieve the collar or segments of collar from the gastrointestinal tract using medical or pharmacological methods. Procedures such as this should be left up to the physician (veterinarian)."

RECOMMENDATIONS: We have reviewed the arguments and deem it appropriate to remove the statement "induce vomiting" from the label. The new label submitted contains the correct first aid statements for acute oral exposure.

DP BARCODE: D248074

CASE: 034680

SUBMISSION: S546541

DATA PACKAGE RECORD BEAN SHEET

DATE: 08/03/98 Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION

ACTION: 305 TECH-LEL REV AMND DATA RE

RANKING : 10 POINTS ()

CHEMICALS: 097805 Deltamethrin

4.0000%

ID#: 068451-00001 DELTAMETHRIN 4% COLLAR

COMPANY: 068451 HOECHST ROUSSEL VET S.A.

PRODUCT MANAGER: 03 SUSAN LEWIS 703-305-7448 ROOM: CM2 PM TEAM REVIEWER: BETH EDWARDS 703-305-5400 ROOM: CM2 206

RECEIVED DATE: 07/09/98 DUE OUT DATE: 01/15/99

* * * DATA PACKAGE INFORMATION * * *

EXPEDITE: N DATE SENT: 08/03/98 DATE RET.: / / DP BARCODE: 248074

CHEMICAL: 097805 Deltamethrin

P TYPE: 001 Submission Related Data Package

11-31-98 CSF: Y LABEL: Y ADMIN DUE DATE: 12/31/98 mcck ASSIGNED TO DATE IN DATE OUT

DIW : RD BRAN: TRB SECT: TOX REVR :

CONTR:

NEGOT DATE: PROJ DATE:

* DATA REVIEW INSTRUCTIONS * * *

Please review information submitted to support the revision of the First Aid Statement for the subject product to delete "induce vomiting."

MRID No. 445787-01

Thanks, Beth Edwards 305-5400

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC 248072 IB/PM03

BRANCH/SECTION DATE OUT 08/03/98

DUE BACK 12/31/98 INS Y

CSF LABEL Y Y

Corenow

EFFICACY STUDY REVIEW

by Kevin J. Sweeney, Entomologist - IB

To: Beth Edwards

Date: September 15, 1998

EPA Reg. or File No.: 68451-1

Product Name: Deltamethrin 4% Collar

Registrant: Hoechst Roussel Vet

PM: George LaRocca

Action: 305

Submission No. S546541

DP #: D248072

Chemical: deltamethrin 4%

Studies Submitted:

MRID # 44578702 Review of the Anti-feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies

MRID # 44578703 Initial "Kill" Activity of Deltamethrin 4% Collars Against Ixodes scapularis Nymphs using Treated Dog Hair as the Testing Substance

MRID # 44578704 Report of Laboratory Trials on the efficacy of Deltamethrin 4% Dog Collars for Control of Ticks - Ixodes ricinus and Rhipicephalus sanguineus in Dogs

MRID # 44602901 Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for control of Ticks - *Ixodes ricinus* and *Rhipicephalus sanguineus*.

MRID # 44578705 Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality, and Blood feeding of Adult *Aedes aegypti* Mosquitoes.

Comments:

The registrant wishes to add deer ticks and mosquitoes to the label.

Based on the submitted studies, the addition of the claims for "deer ticks" is acceptable, black-legged ticks I also acceptable. However, if a species name specific claim is made - then only *Ixodes scapularis* and/or *Ixodes pacificus* may be used in addition to the terms above. *Ixodes sp.* is not acceptable, should be removed and the above species names should replace it.

The label claim for mosquitoes reads: "Collar kills and repels mosquitoes and prevents them from feeding." The data submitted do not support these claims and for the following reasons they should be removed from the label:

- 1. The data do not show that this product is an efficacious repellent. The study results demonstrate a reduction in blood-feeding but this reduction is insufficient to support repellent claims. The maximum reduction in feeding between the control and treated groups is 84.4% with a range of 15.9% to 84.4%. In addition, there was no statistically significant difference in landings between treated and control groups.
- 2. The data do not support the "kill" claim for mosquitoes. The range was 69% 91.1%. The 91.1% mortality result was for one data point only. All other measurements of mortality were below 90%. This is less than the 95% required by Subdivision G Guidelines.

I do not think we should entertain "aids in" claims for any repellent product or one meant to kill any public health pest feeding on a host.

DP BARCODE: D248072

CASE: 034680 DATA PACKAGE RECORD

BEAN SHEET

DATE: 08/03/98

Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION

SUBMISSION: S546541

ACTION: 305 TECH-LBL REV AMND DATA RE

RANKING : 10 POINTS ()

CHEMICALS: 097805 Deltamethrin

4.0000%

ID#: 068451-00001 DELTAMETHRIN 4% COLLAR

COMPANY: 068451 HOECHST ROUSSEL VET S.A.

PRODUCT MANAGER: 03 SUSAN LEWIS 703-305-7448 ROOM: CM2 217 PM TEAM REVIEWER: BETH EDWARDS 703-305-5400 ROOM: CM2 206

RECEIVED DATE: 07/09/98 DUE OUT DATE: 01/15/99

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 248072 EXPEDITE: N DATE SENT: 08/03/98 DATE RET.:

CHEMICAL: 097805 Deltamethrin

P TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y

ASSIGNED TO DATE DATE OUT ADMIN DUE DATE: 12/31/98 IN NEGOT DATE: DIV : RD PROJ DATE:

BREN: IB SWEET: PMO3

REVR : CONTR:

* DATA REVIEW INSTRUCTIONS * * *

attn: Efficacy

Please review studies submitted to support claims for deer ticks and mosquitoes.

MRID Nos. 445787-02; -03; -04; -05; and 446029-01.

Thanks, Beth

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

BRANCH/SECTION DATE OUT DUE BACK DP BC INS CSF LABEL

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

HOECHST ROUSSEL VET S.A. 30 INDEPENDENCE BLVD. P.O. BOX 4915 WARREN, NJ 07059

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/10/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mai JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar, EPA Reg. No. 68451-1

Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Colar. In brief, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the following in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently
 registered label are shown with a line drawn through them, while the words added to
 the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

2. Regulatory action in support of which this package is submitted:

Amended registration of Deltamethrin 4% Collar

3. Transmittal date:

June 1, 1998

4. List of submitted studies:

Cover Letter

Volume 1: John J. Lauber (1998), Revision of Deltamethrin 4%-Collar First Aid Statement (EPA Guideline No. N/A). (MRID. No. 44578701)

Volume 2: R. Killick-Kendrick (1997), Review of the Anti-Feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies (EPA Guideline No.91-3).

(MRID No.44578702)

Volume 3: R. L. Slone (1998), Initial "Kill" Activity of Deltamethrin 4% Collars Against Ixodes scapularis Nymphs using Treated Dog Hair as the Testing Substrate (EPA Guideline No.91-3). (MRID No.44578703)

Volume 4: A. Liebisch and U. Reimann (1997), Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.44578704)

Volume 5: A. Liebisch and U. Reimann (1997), Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars of Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No. 44602901

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult Aedes aegypti Mosquitoes (EPA Guideline No.____).

(MRID No.4457870__)

5. Company Official: John J. Lauber, Ph.D.

Name

6. Company Name: Hoechst Roussel Vet

P. O. Box 4915

Warren, N.J. 07059

Signature

7. Company Contact: John J. (Jack) Lauber, Ph.D.

Phone: 908/231-3426 FAX: 908/231-4462 Turesa,

7/10

The pages in German (25-182) were raw data. The registrant said this was not really necessary for review and so I have taken them out. They faxed me a replacement for page I to say "page I of 24" instead of "... 182".

Please Send to SIG for mRID. Thanks, Beth E.

Administrative

Materials

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

HOECHST ROUSSEL VET S.A. 30 INDEPENDENCE BLVD. P.O. BOX 4915 WARREN, NJ 07059

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/10/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [05] :

* An English translation is required for all work originally reported in other languages.

SIG — See me if you have any questions about this resultanission:

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar, EPA Reg. No. 68451-1
Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Collar. In brief, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the **following** in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently
 registered label are shown with a line drawn through them, while the words added to
 the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

2. Regulatory action in support of which this package is submitted:

Amended registration of Deltamethrin 4% Collar

3. Transmittal date:

June 1, 1998

4. List of submitted studies:

Cover Letter

Volume 1: John J. Lauber (1998), Revision of Deltamethrin 4% Collar First Aid Statement (EPA Guideline No. N/A). (MRID No. 44578701)

Volume 2: R. Killick-Kendrick (1997), Review of the Anti-Feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies (EPA Guideline No.91-3). (MRID No.44578702)

Volume 3: R. L. Slone (1998), Initial "Kill" Activity of Deltamethrin 4% Collars Against Ixodes scapularis Nymphs using Treated Dog Hair as the Testing Substrate (EPA Guideline No.91-3).

(MRID No.44578703)

Volume 4: A. Liebisch and U. Reimann (1997), Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) in Dogs (EPA Guideline No.91-3).

(MRID No.44578704)

Volume 5: A. Liebisch and U. Reimann (1997), Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.Reject (05)

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult *Aedes aegypti* Mosquitoes (EPA Guideline No.____).

(MRID No.44578705)

Company Name:

5. Company Official: John J. Lauber, Ph.D.

Name

Hoechst Roussel Vet

P. O. Box 4915

Warren, N.J. 07059

7. Company Contact:

6.

John J. (Jack) Lauber, Ph.D.

Phone: 908/231-3426 FAX: 908/231-4462 - 1st code (n)out 7800 305-BE PR F-EF JUN 18 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

HOECHST ROUSSEL VET S.A. 30 INDEPENDENCE BLVD. P.O. BOX 4915 WARREN, NJ 07059

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/10/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [05]:

* An English translation is required for all work originally reported in other languages.

Pgs. 25-/82.

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar, EPA Reg. No. 68451-1

Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Collar. In beef, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the following in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently
 registered label are shown with a line drawn through them, while the words added to
 the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours;

John J. Lauber, Ph.D.

Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

2. Regulatory action in support of which this package is submitted:

Amended registration of Deltamethrin 4% Collar

3. Transmittal date:

June 1, 1998

4. List of submitted studies:

Cover Letter

Volume 1: John J. Lauber (1998), Revision of Deltamethrin 4% Collar First Aid Statement (EPA Guideline No. N/A). (MRID No. 44578701)

Volume 2: R. Killick-Kendrick (1997), Review of the Anti-Feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies (EPA Guideline No.91-3). (MRID No.44578702)

Volume 3: R. L. Slone (1998), Initial "Kill" Activity of Deltamethrin 4% Collars Against Ixodes scapularis Nymphs using Treated Dog Hair as the Testing Substrate (EPA Guideline No.91-3). (MRID No.44578703)

Volume 4: A. Liebisch and U. Reimann (1997), Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.44578704)

Volume 5: A. Liebisch and U. Reimann (1997), Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.Reject (05)

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult Aedes aegypti Mosquitoes (EPA Guideline No.____).

(MRID No.44578705)

5. Company Official: John J. Lauber, Ph.D. Name

ne 🤇 🖊 💚 Signati

6. Company Name: Hoechst Roussel Vet

P. O. Box 4915

Warren, N.J. 07059

7. Company Contact: John J. (Jack) Lauber, Ph.D.

Phone: 908/231-3426 FAX: 908/231-4462

445787-00

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar, EPA Reg. No. 68451-1

Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Collar. In brief, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the following in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently registered label are shown with a line drawn through them, while the words added to the label are shown as underlined text.
- · Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

2. Regulatory action in support of which this package is submitted:

Amended registration of Deltamethrin 4% Collar

3. Transmittal date:

June 1, 1998

4. List of submitted studies:

Cover Letter

Volume 1: John J. Lauber (1998), Revision of Deltamethrin 4% Collar First Aid Statement (EPA Guideline No. N/A). (MRID No. 44578701)

Volume 2: R. Killick-Kendrick (1997), Review of the Anti-Feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies (EPA Guideline No.91-3). (MRID No.44578702)

Volume 3: R. L. Slone (1998), Initial "Kill" Activity of Deltamethrin 4% Collars Against Ixodes scapularis Nymphs using Treated Dog Hair as the Testing Substrate (EPA Guideline No.91-3), (MRID No.44578703)

Volume 4: A. Liebisch and U. Reimann (1997), Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.44578704)

Volume 5: A. Liebisch and U. Reimann (1997), Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.Reject (05)

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult Aedes aegypti Mosquitoes (EPA Guideline No.____).

(MRID No.4457870=)

5. Company Official: John J. Lauber, Ph.D. Name

6. <u>Company Name:</u> Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

7. Company Contact: John J. (Jack) Lauber, Ph.D. Phone: 908/231-3426

FAX: 908/231-4462

(A) SEP	United States Env Office of Pest Wash Applica	vironmental Protection ticide Programs (H78 sington, DC 20460 ation for Pest	505C) X	Registra Amendr Other	- 10 "W AND ADDRESS	Number 63 132
		Section I				
1. Company/Product Numl	ber coars 1	10 2.0	EPA Product Manage		3. Proposed Classifi	ication
	68451-2		LaRocca/13	03	None	Restricte
4. Company/Product (Nam	18)	~ P	W#		THOME T	Mastricia
	tamethrin 4% Colla		13 03		1	
5. Name and Address of A	pplicant (Include ZIP Code)				nce with FIFRA Section ical in composition and	
Hoechst Rous		T to	o:	minat of Marit	car in composition and	a lavell
Agent for Ho 30 Independe	echst Roussel Vet S.A.			4		
P.O. Box 491		E	PA Reg. No			
Warren, N.J.	12 E 1 C 1 C 1 C 1 C 1 C 1 C 1 C 1 C 1 C 1	P	roduct Name	320		
		Section I I				
y Amendment - Explain	below		Final printed label		0	
^	onse to Agency letter dated_	_	Agency letter date	ed		-
			"Me Too" Applicate	ion.	**	
Notification - Explain b	elow.		Other - explain be	low.	14:	
Label revision: 1. First Aid St 2. Directions t	tatement - deleting for Use - addition	of claims fo		and mosqui	toes 445787.	
First Aid St Directions to Material This Product to Child-Resistant Packaging	for Use - addition Will Be Packaged In: Unit Packaging	of claims fo		2. Type of C	445787.	
1. First Aid St 2. Directions t	for Use - addition	of claims fo	r deer ticks	2. Type of C	445787.	
First Aid St Directions to Material This Product to Child-Resistant Packaging	for Use - addition Will Be Packaged In: Unit Packaging	Section III	r deer ticks	2. Type of C	Container Metal Plastic Glass	
1. First Aid St 2. Directions to 2. Directions to 1. Material This Product to Child-Resistant Packaging Yes* No	Will Be Packaged in: Unit Packaging Yes No	Section III Water Solution Yes No per If "Yes,"	uble Packaging	2. Type of C	Container Metal Plastic Glass Paper	
1. First Aid St 2. Directions to 2. Directions to 1. Material This Product to Child-Resistant Packaging Yes* No Certification must be	Will Be Packaged in: Unit Packaging Yes No	Section III Water Soli	uble Packaging	2. Type of C	Container Metal Plastic Glass	
1. First Aid St 2. Directions to 2. Directions to 1. Material This Product to Child-Resistant Packaging Yes* No	Will Be Packaged in: Unit Packaging Yes No If "Yes," Unit Package wgt.	Section III Water Solution Yes No per If "Yes,"	uble Packaging No. per container	2. Type of C	Container Metal Plastic Glass Paper Other (Specify)	
1. First Aid St 2. Directions to 2. Directions to 1. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents	Will Be Packaged in: Unit Packaging Yes No If "Yes," Unit Package wgt.	Section III Water Soli Yes No per lit "Yes." Package w	uble Packaging No. per container	2. Type of C	Container Metal Plastic Glass Paper Other (Specify)	
1. First Aid St 2. Directions to 2. Directions to 1. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents	Will Be Packaged in: Unit Packaging Yes No If "Yes," Unit Package wgt. Information 4. Size	Section III Water Soli Yes No per If "Yes," Package we re(s) of Retail Contain	uble Packaging No. per container	2. Type of C	Container Metal Plastic Glass Paper Other (Specify)	
1. First Aid St 2. Directions to 2. Directions to 1. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label	Will Be Packaged in: Unit Packaging Yes No If "Yes," Unit Package wgt. Information 4. Size	Section III Water Soli Yes No It "Yes," Package we se(s) of Retail Contains	uble Packaging No. per container iner 5.	2. Type of C	Container Metal Plastic Glass Paper Other (Specify)	
1. First Aid St 2. Directions to 2. Directions to 3. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label Co. Manner in Which Label I	Will Be Packaged in: Unit Packaging Yes No If "Yes," Unit Package wgt. Information Sontainer S Affixed To Product	Section III Water Solution Yes No Per It "Yes," Package we seed of Retail Container Lithograph Paper glued Stenciled Section IV	uble Packaging No. per container Other (2. Type of C	Container Metal Plastic Glass Paper Other (Specify) sel Directions ag accompanying product	
1. First Aid St 2. Directions to 2. Directions to 3. Material This Product to Child-Resistant Packaging Yes* No Certification must be uhmitted. Label Contents Label Contents Manner In Which Label I	Will Be Packaged in: Unit Packaging Yes No If "Yes," Unit Package wgt. con sinformation 4. Size	Section III Water Solution Yes No Package water Teles of Retail Contain Lithograph Paper glued Stenciled Section IV ntification of individual	uble Packaging No. per container Other (Location of Labelin	Container Metal Plastic Glass Paper Other (Specify) sel Directions ag accompanying product	
1. First Aid St 2. Directions to 2. Directions to 3. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label Contents Manner In Which Label II. 1. Contact Point (Complete Name)	Will Be Packaged in: Unit Packaging Yes No If "Yes," Unit Package wgt. Information Sontainer S Affixed To Product	Section III Water Sole Yes No Per It "Yes," Package w te(s) of Retail Contain Lithograph Paper glued Stenciled Section IV ntification of individual Title	uble Packaging No. per container Other (2. Type of C	Container Metal Plastic Glass Paper Other (Specify) sel Directions ag accompanying product	
1. First Aid St 2. Directions to 2. Directions to 3. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label Contents Manner In Which Label II. 1. Contact Point (Complete Name)	Will Be Packaged in: Unit Packaging Yes No If Yes, No. Unit Package wgt. con container s Affixed To Product items directly below for iden Lauber Ph.D.	Section III Water Solution Yes No Partial Contain Lithograph Paper glued Stenciled Section IV ntification of individual Title Manager	uble Packaging No. per container Other (2. Type of C	Container Metal Plastic Glass Paper Other (Specify) el Directions g accompanying product cess this application.) elephone No. (Include A 908-231-3426	krea Co
1. First Aid St 2. Directions to 2. Directions to 3. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label Contents Manner In Which Label to 1. Contact Point (Complete Name John J.	Will Be Packaged in: Unit Packaging Yes No If "Yes," Unit Package wgt. Container S Affixed To Product items directly below for iden Lauber Ph.D. Certifi	Section III Water Solution Yes No Package water stainer Lithograph Paper glued Stenciled Section IV ntification of individual Title Manager	while Packaging No. per container Tother (2. Type of C	Container Metal Plastic Glass Paper Other (Specify) Plastic Glass Paper Other (Spec	krea Co
1. First Aid St 2. Directions if 2. Directions if 1. Material This Product if Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label Contents Manner in Which Label II 1. Contact Point (Complete lame John J. I certify that the statement	Will Be Packaged in: Unit Packaging Yes No If Yes," No. Unit Package wgt. con Sontainer S Affixed To Product Sitems directly below for iden Lauber Ph.D. Certificate I have made on this form a	Section III Water Solution Per If "Yes." Package was read of Retail Container Lithograph Paper glued Stenciled Section IV It it was read of Individual Title Manager Manager Indication Manager	while Packaging No. per container Tother (2. Type of C	Container Metal Plastic Glass Paper Other (Specify) el Directions g accompanying product cess this application.) elephone No. (Include A 908-231-3426	Area Co
1. First Aid St 2. Directions if 2. Directions if 1. Material This Product if Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label Contents Manner in Which Label II 1. Contact Point (Complete lame John J. I certify that the statement	Will Be Packaged in: Unit Packaging Yes No If Yes," Unit Package wgt. Container S Affixed To Product A size Items directly below for iden Lauber Ph.D. Certificate I have made on this form a knowingly false or misleading	Section III Water Solution Per If "Yes." Package was read of Retail Container Lithograph Paper glued Stenciled Section IV It it was read of Individual Title Manager Manager Indication Manager	while Packaging No. per container Tother (2. Type of C	Container Metal Plastic Glass Paper Other (Specify) el Directions g accompanying product cess this application.) elephone No. (Include A 908-231-3426	Area Co
1. First Aid St 2. Directions to 2. Directions to 3. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label Contents Manner In Which Label to 1. Contact Point (Complete lane) John J. I certify that the statement acknowledge that any keeps to the content of the content	Will Be Packaged in: Unit Packaging Yes No If Yes," Unit Package wgt. Container S Affixed To Product A size Items directly below for iden Lauber Ph.D. Certificate I have made on this form a knowingly false or misleading	Section III Water Solution Per If "Yes." Package was read a statement may be proposed attachments to statement may be proposed. Section IV Title Manager 3. Title	while Packaging No. per container Tother (2. Type of C Location of Lab On Labelin Cessary, to pro stration atte and complete imprisonment or	Container Metal Plastic Glass Paper Other (Specify)	Area Co
1. First Aid St 2. Directions to 2. Directions to 3. Material This Product to Child-Resistant Packaging Yes* No Certification must be whmitted. Location of Net Contents Label Contact Point (Complete Name John J. I certify that the statement acknowledge that any knowledge that an	Will Be Packaged in: Unit Package wgt. Unit Package wgt. Unit Package wgt. Sontainer S Affixed To Product Sitems directly below for ident Lauber Ph.D. Certificate I have made on this form a showingly false or misleading w.	Section III Water Solution Per If "Yes." Package was read a statement may be proposed attachments to statement may be proposed. Section IV Title Manager 3. Title	while Packaging No. per container Tother (2. Type of C Location of Lab On Labelin Cessary, to pro stration atte and complete imprisonment or	Container Metal Plastic Glass Paper Other (Specify)	Area Co
1. First Aid St 2. Directions to 2. Directions to 3. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label Contact Point (Complete Name John J. I certify that the statement I acknowledge that any k both under applicable law. Signature	Will Be Packaged in: Unit Packaging Yes No If Yes," Unit Package wgt. Container S Affixed To Product A size Items directly below for iden Lauber Ph.D. Certificate I have made on this form a knowingly false or misleading	Section III Water Sold Yes No Per It "Yes," Package we retainer Package we retained Stenciled Section IV stiffication of individual Title Manager and all attachments to statement may be possible of the package we retained to the package we retained to the package we retained and all attachments to statement may be possible of the package we retained all attachments to statement may be possible or the package we retain the package	whee Packaging No. per container Tother (2. Type of C Location of Lab On Labelin Cessary, to pro stration atte and complete imprisonment or	Container Metal Plastic Glass Paper Other (Specify)	Area Co
1. First Aid St 2. Directions to 2. Directions to 3. Material This Product to Child-Resistant Packaging Yes* No Certification must be ubmitted. Location of Net Contents Label Co. Manner in Which Label to Manner in Which Label to I. Contact Point (Complete land) I certify that the statement acknowledge that any k both under applicable land. Signature	Will Be Packaged in: Unit Package wgt. Unit Package wgt. Unit Package wgt. Sontainer S Affixed To Product Sitems directly below for ident Lauber Ph.D. Certificate I have made on this form a showingly false or misleading w.	Section III Water Sold Yes No Per It "Yes," Package we retainer Package we retained Stenciled Section IV stiffication of individual Title Manager and all attachments to statement may be possible of the package we retained to the package we retained to the package we retained and all attachments to statement may be possible of the package we retained all attachments to statement may be possible or the package we retain the package	while Packaging No. per container Tother (2. Type of C Location of Lab On Labelin Cessary, to pro stration atte and complete imprisonment or	Container Metal Plastic Glass Paper Other (Specify)	Area Co

SEPA Env	States tection Agency DC 20460	ncy Registr Amend Other		711	254630	
	Appl	ication for Pesticide - !	Section	T.		:#:
1. Company/Product Number		2. EPA Product	Manager		г	d Classification
4. Company/Product (Name)		PM#			None	Restricted
5. Name and Address of Applicant Check if this is a n			luct is sin			A Section 3(c)(3) ition and labeling
		Section - II				
Notification - Explain below		December 1	- Explain b	elow.		
		Section - III				
1. Material This Product Will Be Pa		The second second		To an analysis		
No If "Y			per tainer	P G P	ntainer fetal lastic lass aper ther (Specify	0
3. Location of Net Contents Inform	122,222	e(s) Retail Container	5. L	On Label I On Label		ng product
6. Manner in Which Label is Affixe	d to Product	Lithograph Paper glued Stenciled	Other			
		Section - IV				
1. Contact Point Complete items	directly below for iden	tification of individual to be conta	cted, if ne	cessary, to proce	ss this applic	eation.)
Name		Title		Tel	ephone No.	(include Area Code)
	I have made on this fo	ertification orm and all attachments thereto ar ing statement may be punishable l			1	ete Application occived (Stamped)
2. Signature		3. Title				
4. Typed Name	5. Date	-	-			

254630

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send-comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1: Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a <u>specific EPA-registered product</u>. This section is <u>not to be</u> used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "emend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 8. EPA Use Only.

Pleasa read instructions o	n reverse before comple	ting form.		Form Approved	i. OMB No. 2070-	0060. Approval expires 05-31-98
⊕EPA	Environmenta	United States I Protection Ington, DC 204			Registration Amendment Other	
	1	Applicatio	n for Pesticio	le - Section	n I	1 10
1. Company/Product Num	ber		2. EPA	roduct Manager	20 3	3. Proposed Classification
4. Company/Product (Nam	ne)	1	PM#	- 23		None Restricted
5. Name and Address of A	Applicant (Include ZIP Co	ode)	(b)(i), m to: EPA R	y product is si eg. No ct Name		with FIFRA Section 3(c)(3) in composition and labeling
			Section - I			
Amendment - Expl. Resubmission in re Notification - Expla	sponse to Agency letter	r deted		Final printed lat Agency letter d "Me Too" Appl Other - Explain	cation.	
		VU	Section - II			
1. Material This Product V	The second second		Torrest and a		12	
Child-Resistant Packaging Yes* No Certification must	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No, per , container	Water Soluble Parties Yes No If "Yes" Package wgt	No. per container	PI GI	tainer etal astic ass iper ther (Specify)
3. Location of Net Content	s Information Container	4. Size(s) Ret	ail Container	5. I	ocation of Label D On Label On Labeling	irections accompanying product
6. Manner in Which Label	is Affixed to Product	Lithogr Paper Stencil		Other _		
al an analysis and a second	1		Section - IV			
1. Contact Point Comple	te items directly below t	for identificațio	n of individual to be	contacted, if ne	ecessary, to proces	s this application.)
Name		**	Tide	, market	Tele	phone No. (Include Area Coda)
	tements I have made on any knowingly false or r e law.		all attachments the			6. Date Application Received (Stamped)
2. Signature		= t	3. Title			
4, Typed Name			5. Dete			73

254 30

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption-Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8,5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EIPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s)
for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration
submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 8. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

(A) SEP	United States Environ Office of Pesticid Washingt Application	nmental Protection Agency e Programs (H7505C) on, DC 20460 on for Pesticide:	Registra X Amenda Other	opp Identifier Number
		Section I		
1. Company/Product Numb		2. EPA Produc	. 0	3. Proposed Classification
Company/Product (Nam	68451	G. LaRoco	13 03	None Restricted
Company of the control of the contro	Charles and a substitution of	13 -	03	
	tamethrin 4% Collar	C Eurodine		nce with FIFRA Section 3(c)(3)
Hoechst Rous	ssel Vet echst Roussel Vet S.A. ence Blvd. 5		duct is similar or identi	cal in composition and labeling
Transit, (c.o.		Section I I		
	V-1/		and labels to account	
χ Amendment - Explain I	below		ited labels in response to letter dated	4
Resubmission in respo	onse to Agency letter dated		Application.	
Notification - Explain be	elow.			
		Other - e	xplain below.	
Material This Product W Child-Resistant Packaging		Water Soluble Packagin	ig 2. Type of C	ontainer
Yes*	Yes No	Yes No		Metal Plastic Glass Paper
* Certification must be	Unit Package wgt. Contained	20 Page 10 Pag	No. per container	Other (Specify)
submitted.				10.
	ontainer	of Retail Container	5. Location of Label On Labelin	a companying product
. Manner In Which Label Is	Pa	hograph per glued anciled	Other (
Contact Point (Complete	S	ection IV	ted, if necessary, to pro-	cess this application.)
lame		ection IV	To To	cess this application.) elephone No. (Include Area Code) 908-231-3426
John J.	Lauber Ph.D. Certificates I have made on this form and a nowingly false or misleading state.	ection IV ation of individual to be contact Title Manager, Product tion	Registration	908-231-3426 6. Date Application
John J. I certify that the statement I acknowledge that any kr	Lauber Ph.D. Certificates I have made on this form and a nowingly false or misleading state.	ection IV ation of individual to be contact Title Manager, Product tion all attachments thereto are true tement may be punishable by	Registration	908-231-3426 6. Date Application Received (Stamped)

N

(A) SEPA	United States Environmental Office of Pesticide Progra Washington, DC Application for	Protection Agency ams (H7505C) 20460	Registr X Amend Other	
	Secti	on I		
Company/Product Number	1	2. EPA Product A		3. Proposed Classification
	451-2	G. LaRocca	/13 —	None Restricted
4. Company/Product (Name)	*	PM#	2 - 2	Thous Thestricted
	hrin 4% Collar	-13 6		
5. Name and Address of Applicant Hoechst Roussel Ve Agent for Hoechst I 30 Independence BI P.O. Box 4915 Warren, N.J. 07059	et Roussel Vet S.A. vd.			ance with FIFRA Section 3(c)(3) Itical in composition and labeling
- Valigary in the second	Section			
Amendment - Explain below Resubmission in response to A				to (-)
Notification - Explain below.		. Other - exp	lain below.	
2. Directions for Us	e - addition of clai		cks and mosqu	itoes.
Material This Product WIN Be P Child-Resistant Packaging Unit Packaging Yes*	Section Sectional Section Sect		2. Type of	Container Metal Plastic Glass
1. Material This Product WIN Be P Child-Resistant Packaging Unit Pa Yes* No If "Yes, Unit Pa	Section Section Section Section Section Section Section No. per lif	lill Vater Soluble Packaging Yes No Yes,* No		Container Metal Plastic
1. Meterial This Product Will Be P Child-Resistant Packaging Unit Pa Yes* No If "Yes, Unit Pa Location of Net Contents Informat Label Container	Section Section Section Section Section We see	ater Soluble Packaging Yes No Yes, No ackage wgt. con	2. Type of	Container Metal Plastic Glass Paper Other (Specify)
1. Material This Product WIN Be P Child-Resistant Packaging Unit Pa Yes* No If "Yes, Unit Pa Submitted, Location of Net Contents Informat Label Container	Section Section Section Section Section Vers No. per container Product To Product Lithograph Paper glue Stenciled	Atter Soluble Packaging Yes No Yes, No Ackage wgt. container	2. Type of	Container Metal Plastic Glass Paper Other (Specify)
1. Material This Product Will Be P Child-Resistant Packaging Unit Pa Yes* No If "Yes, Unit Pa Submitted. Location of Net Contents Informat Label Container 6. Manner In Which Label is Affixed	Section Section Section Section Yes No No. per container Product To Product Lithograph Paper glue Stenciled Section	Atter Soluble Packaging Yes No Yes, No ackage wgt. container Id Container	2. Type of	Container Metal Plastic Glass Paper Other (Specify) bel Directions ng accompanying product
1. Material This Product Will Be P Child-Resistant Packaging Unit Pa Yes* No * Certification must be submitted. Location of Net Contents Informat Label Container 6. Manner In Which Label is Affixed	Section Section Section Section Ves No No. per container Product To Product Lithograph Paper glue Stenciled Section Title	Atter Soluble Packaging Yes No Yes, No ackage wgt. container Id Container	2. Type of	Container Metal Plastic Glass Paper Other (Specify) bel Directions ing accompanying product occess this application.) Telephone No. (Include Area Code) 908-231-3426
1. Material This Product Will Be P Child-Resistant Packaging Unit Pa Yes* No Certification must be Location of Net Contents Informat Label Container 6. Manner In Which Label is Affixed 1. Contact Point (Complete items di	Section Section Section Section Ackaging Yes No No. per if container Package wgt. To Product Lithograph Paper glue Stenciled Section Frectly below for identification of items Certification made on this form and all attact	ater Soluble Packaging Yes No Yes, No ackage wgt. con It Container It Ottoriolisticual to be contacted ager, Product	2. Type of	Container Metal Plastic Glass Paper Other (Specify) bel Directions Ing accompanying product rocess this application.) Telephone No. (Include Area Code) 908-231, 3426 6. Date Application Received
1. Material This Product Will Be P Child-Resistant Packaging Yes* No * Certification must be submitted. Location of Net Contents Informat Label Container 6. Manner In Which Label is Affixed 1. Contact Point (Complete items di Name John J, Laub Locatiny that the statements I have Lacknowledge that any knowingly	Section Section Section Section Section Yes No No. per ontainer Section 4. Size(s) of Retained Faper glue Stenciled Frectly below for identification of the container Certification made on this form and all attact false or misleading statement of the container 3. Title	III Jater Soluble Packaging Yes No Yes, No ackage wgt. con ackage wgt. con ackage wgt. con all Container In IV Individual to be contacted ager, Product ments thereto are true, may be punishable by file anager, Product	2. Type of	Container Metal Plastic Glass Paper Other (Specify) bel Directions Ing accompanying product ocess this application.) Telephone No. (Include Area Code) 908-231, 3426 6. Date Application Received (Stamped)

(A) SEP	Office Office	of Pesticide Progr Washington, DC	Protection Agency rams (H7505C)		ration	Approval expires 11-30-9: OPP Identifier Number 166132
		Sect	lion I			
1. Company/Product Numb			2. EPA Product	Manager	3. P	roposed Classification
	68451 - 1		G. LaRocca	1/13	$\Box \Box$	l. 🗀
Company/Product (Name De I †	amethrin 4%	Collar	PM# 13			None Restricted
5. Name and Address of Ap Hoechst Rous	oplicant (Include ZIP) sel Vet chst Roussel Vet nce Blvd.	Code)				FIFRA Section 3(c)(3) emposition and labeling
		Section	on ()			
Amendment - Explain to Resubmission in respo	nse to Agency letter		Final prints Agency le "Me Too"	ed labels in response ther dated	e to	
		Section	un :			
1. Material This Product W	/III Be Packaged in:					
Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging	2. Type o	f Container	
Yes*	Yes No		Yes No		Metal Plastic Glass	
* Certification must be	If "Yes," Unit Package wgt.			o. per	Paper Other (Sp	-
		1		A NAZITO		pecify)
Label Contents	ontainer	4. Size(s) of Re	tail Container	5. Location of L	abel Directi	
Label Cale	ontainer	4. Size(s) of Re	tail Container	5. Location of L	abel Directi	ons
Label Contents 6. Manner In Which Label Is	ontainer Affixed To Product	4. Size(s) of Re Lithograp Paper glu Stenciled	tail Container	5. Location of L On Labo On Labo ther (abel Directi el eling accom	ons panying product
submitted. Label Cabel Cabel is Manner in Which Label is Contact Point (Complete	ontainer Affixed To Product items directly below	4. Size(s) of Re Lithograp Paper glu Stenciled Section for identification of	tail Container	5. Location of L On Labe On Labe ther (abel Directi el eling accom process this	panying product application.)
Label Contents Label Contents Label Contents Manner In Which Label Is 1. Contact Point (Complete	items directly below the Ph.D. Is I have made on this nowingly false or mis	4. Size(s) of Re Lithograp Paper glu Stenciled For identification of Title Mic	tail Container on IV findividual to be contacte anager, Product chments thereto are true,	5. Location of L On Labe On Labe on Labe ad, if necessary, to	abel Direction of the state of	panying product application.) No. (Include Area Code)
Label Contents Label Contents Label Contents Label Contents Manner in Which Label is 1. Contact Point (Complete Name John J. Lau I certify that the statement I acknowledge that any kn	items directly below the Ph.D. Is I have made on this nowingly false or mis	4. Size(s) of Re Lithograp Paper glu Stenciled Section for identification of Title Mi Certification s form and all attaces sleading statement 3. T	tail Container on IV findividual to be contacte anager, Product chments thereto are true, t may be punishable by	5. Location of L On Labe On Labe on Labe ad, if necessary, to Registration accurate and compline or imprisonment	abel Direction of the process this Telephone 908-2	panying product application.) No. (Include Area Code) 231-3426 Date Application Received
Label C. Label C. Label C. 6. Manner In Which Label Is 1. Contact Point (Complete Name John J. Lau I certify that the statement I acknowledge that any knowledge that any knowledg	items directly below the Ph.D. Is I have made on this nowingly false or mis	4. Size(s) of Re Lithograp Paper glu Stenciled Section for identification of Title Mi Certification s form and all attacks sleading statement 3. T Mi 5. D	tail Container on IV findividual to be contacte anager, Product chments thereto are true t may be punishable by	5. Location of L On Labe On Labe on Labe ad, if necessary, to Registration accurate and compline or imprisonment	abel Direction of the process this Telephone 908-2	panying product application.) No. (Include Area Code) 231-3426 Date Application Received

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

October 17, 1997

Mr. John Lauber Hoechst Roussel Vet Agent for Hoechst Roussel Vet S.A. 30 Independence Blvd. Warren, N.J. 07059

Dear Mr. Lauber:

Subject:

Amendment - Efficacy Claims, Compliance with PRN 96-6

Deltamethrin 4% Dog Collar

EPA Reg. No. 68451-1

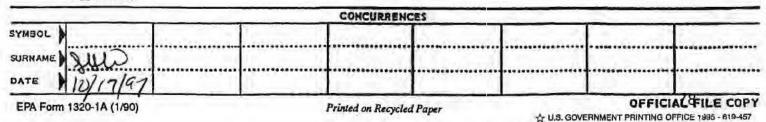
Your June 16, 1997 Submission

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy of the labeling is enclosed for your records.

Sincerely,

George T. LaRocca Product Manager (13) Insecticide-Rodenticide Branch Registration Division (7505C)

Enclosure



¥6

KECU EPA/OPP/OP

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

ACTIVE INGREDIENT:

Deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate]

INERT INGREDIENTS

Total

Percentage by Weight

4.0%

96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 1.1 oz

ACCEPTED

OCT 1 7 1997

Under the Federal Insecticide.
Fungicide, and Rodenticitide Act.
as amended, for the posticide
registered under
EDE Res. No. 1845/-/

Hoechst Roussel Vet SA 102 route de Noisy 93235 Romainville, France

page 1 of 3 13 June 1997

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterianarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2 -3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus) and American dog tick (Dermacentor variabilis). This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET S.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

The Hoechst Name and logo are registered trademarks of Hoechst AG.

© 1997 HRV S.A.

Part No. XXXXX

Universal Product Code Number (Bar Code)

page 3 of 3 13 June 1997 97 06 13a

(A) SEP	A United States Office of W Appl	Environmental Pro Pesticide Program: fashington, DC 20 ication for F	otection Agency s (H7505C) 460 Zesticide:	Registration Amendmen Other	25	fier Number 433 3132
	- PF	Saction		- 12	O	(#
Company/Product Numb	68451 — /		2. EPA Product Manager G. LaRocca/13	3.	Proposed Cla	Silication
4. Company/Product (Nam		11	PM# 13	L	None	Restricted
5. Name and Address of A Hoechst Rous	pplicant (Include ZIP Co ssel Vet echst Roussel Vet : nce Blvd. 5	de) .	6. Expedited Review. (b)(i), my product is sinta: EPA Reg. No. 360 Product Name	nilar or identical in	composition	
		Section I			2	À
X Amendment - Explain Resubmission in respo	below onse to Agency letter da	ted	Final printed labels Agency letter date	d	19 P.	1/8 d0,
Notification - Explain b			"Me Too" Application Other - explain bek		4 00	P/0P01
Material This Product V Child-Resistant Packaging	VIII Be Packaged in:	Section III	er Soluble Packaging	2. Type of Contain	ner	
Yes*	Yes No		Yes No	Metal Plastic Glass Paper		
	If "Yes," Unit Package wgt.	No. per If "Y			(Specify)	
		container Pack	kage wgt. container		(opoul) <u>r</u>	
bmitted. Location of Net Contents		Size(s) of Retail		ocation of Label Din	ections .	luct
Label Contents	Information 4.		Container 5. L	On Label	ections .	duct
bmitted. B. Location of Net Contents Label Contents Manner in Which Label is	Information 4. container s Affixed To Product	Size(s) of Retail Lithograph Paper glued Stenciled Section I	Container 5. L	On Label On Labeling acco	ections ompanying proc	د
Label Contents Label Contents Contact Point (Complete	Information 4. container s Affixed To Product	Size(s) of Retail (Lithograph Paper glued Stenciled Section I identification of incomplete the section of incomplete the	Container 5. L	On Labeling according acco	ections ompanying proc) le Area Code
bmitted. B. Location of Net Contents Label C. B. Manner in Which Label Is 1. Contact Point (Complete Name John J. I certify that the statement	Information 4. container s Affixed To Product items directly below for Lauber Ph.D. Container Lauber Ph.D.	Size(s) of Retail of Retai	Container 5. L Other (On Label On Labeling according accor	ections companying process this application one No. (Include	e Area Code
Label Contents Label Co. Manner in Which Label Is Contact Point (Complete Name John J. I certify that the statement Lacknowledge that any is	Information 4. container s Affixed To Product items directly below for Lauber Ph.D. Container Lauber Ph.D.	Size(s) of Retail of Retai	Container 5. L Other (On Label On Labeling according accor	this application. one No. (Include 3-231-3426	e Area Code

B

(A) SEPA	United States Envir Office of Pestic Washin Applicat	onmental Protectide Programs (ington, DC 2046) ion for Pe	etion Agency 47505G) X	Registration Amendment Other	152 534
		Section I			
1. Company/Product Number	C0454		2. EPA Product Manages	3.	Proposed Classification
	68451		G. LaRocca/13		None Restricted
4. Company/Product (Name)		-	Participants		
	ethrin 4% Collar	•	13	للبجسيا	
5. Name and Address of Application Hoechst Roussel Agent for Hoechs 30 Independence P.O. Box 4915 Warren, N.J. 070	Vet st Roussel Vet S.A. Blvd.				with FIFRA Section 3(c)(3) n composition and labeling
		Section II			
X Amendment - Explain below	*		Final printed labels Agency letter date		
Notification - Explain below		4	"Me Too" Application Other - explain belo		42
Material This Product Will B Child Product Will B	le Packaged In:	Section III	,	10.7	
	it Packaging		ioluble Packaging	2. Type of Contain	
Yes*	Yes	ΙДΥ	•	Metal Plasti	
L No	No	L N		Glass	
	/es," No. ; t Package wgt. conta				(Specify)
3. Location of Net Contents Infor		s) of Retail Con	tainer 5. t	ocation of Label Din On Label On Labeling acc	ections companying product
6. Manner in Which Label is Affi,	and the state of t	Lithograph Paper glued Stanciled	Other (_		
		Section IV			
1. Contact Point (Complete item	s directly below for identifi	Title	tual to be contacted, if nec		
Name John J. La	uber Ph.D.		r, Product Regis		one No. (Include Area Code) 3-231-3426
I certify that the statements I had acknowledge that any knowledge that any knowledge that any knowledge.		d all attachment			6. Date Application Received (Stamped)
. Signature	iuler	3. Title Manag	er, Product Regi	stration	
. Typed Name		5. Date			
John J. La	uber	June	16, 1999		/

d

.

CEPA Office of	Environmental Pro Pesticide Programs Vashington, DC 20- lication for P	otection Agency s (H7505C) 460	Registra X Amenda Other	112 3 3 12
	Section			
Company/Product Number		2. EPA Product		3. Proposed Classification
68451		G. LaRocci	a/13	None Restricted
4. Company/Product (Name) Deltamethrin 4% Co	llar	13		
5. Name and Address of Applicant (Include ZIP Co Hoechst Roussel Vet Agent for Hoechst Roussel Vet 30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059			uct is similar or ident	nce with FIFRA Section 3(c)(3) loal in composition and labeling
	Section I			
χ Amendment - Explain below			ed labels in response t	•
Resubmission in response to Agency letter da	ted		tter dated	
		"Me Too"	Application.	
lotification - Explain below.		Other - ex	plain below.	
	Section III	, 5.		
Material This Product Will Be Packaged In:	1		10.3	
Child-Resistant Packaging Unit Packaging	Wate	r Soluble Packaging	2. Type of C	
		Yes		Metal Plastic
L No L No		No	o =	Glass Paper
* Unit Package wgt.	No. per ontainer Pack	Total Control of the	o. per entainer	Other (Specify)
3. Location of Net Contents Information 4.	Size(s) of Retail C	Container -	5. Location of Late	
6. Manner In Which Label Is Affixed To Product	Lithograph		ther (g accompanying product
	Paper glued Stendiled			
	Section IV			
Contact Point (Complete items directly below for	-	vidual to be contacte		
John J. Lauber Ph.D.	Manag	ger, Product	Registration	elephone No. (Include Area Code) 908-231-3426
	ertification rm and all attachme	ents thereto are true.	accurate and complet	6. Date Application Received (Stamped)
I certify that the statements I have made on this to I acknowledge that any knowingly false or misles both under applicable law.	ding statement may	be punishable by 1	ine or imprisonment or	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
I acknowledge that any knowingly false or misles both under applicable law.	ding statement may		t Registration	
I acknowledge that any knowingly false or misles both under applicable law. 2. Signature	3. Title Ma.na 5. Date			

SEPA Environmental Protection A Washington, DC 20460			ion Agency		Registrat Amendm Other		OPP Identifier Number 254334
The Part of		Applicat	ion for Pasticida -	Section	il.		
1. Company/Product Number	or T		2. EPA Produ	ct Manager		3. Pr	oposed Classification
4. Company/Product (Name	, -		PM#			10	None Restricted
5. Name and Address of Ap	plicant <i>(Include ZIP C</i>	odel		oduct is sir			FIFRA Section 3(c)(3) mposition and labeling
Resubmission in responsible Notification - Explain Explanation: Use addition	oonse to Agency lette below.		Age "Me	I primed 1=0 ncy letter d Too" Appli er - Explain t	canon	to	
		1	Section - III				
1. Material This Product Wil	A CARLO STEEL AND THE	1	Water Soluble Facker	>	To 200 40		
Child-Resistant Packaging Yes* No	Unit Packaging Yes No	1	Yes No		2. Type of C	Metal Plastic Glass Paper	3
Certification must submitted	If "Yes" Unit Packaging wgt	. No. per	Package wgt or	o. per ontainer		Other (S	Specify)
3. Location of Net Contents	Information Container	4. Size(s) A	atail Container	5. L	On Labelin	4	ne panying product
6. Manner in Which Label is	Affixed to Product	Lithe	r gloed oiled	Other			
		Sten	Section - IV				
1. Contact Point Complete	items directly below	for identifical		if ne	cessary, to pro	cess this	application.)
Name			Title			Telephon	e No. (Include Area Code)
	ny knowingly false or		nation d all attachments thereto stement may be punishable				6. Date Application Received (Stamped)
2. Signature			3. Title				
4. Typed Name			5. Date				

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing date sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Weshington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mackup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been essigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must authorize an authorize from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 8. EPA Use Only.

Please read instructions on re-	rerse before complet	ting form.		Form Approved	. OMB No. 2070-	0060. Appro	val expires 05-31-98
≎EPA	nvironmental Washin	ngton, DC 20	460		Registratio Amendmer Other	2	54334
	-11	Application	on for Pestici	de - Section	11		
1. Company/Product Number			2. EPA	Product Manager		3. Proposed	
4. Company/Product (Name)			PM#			None	Restricted
5. Name and Address of Appli	cant (Include ZIP Cod	del	(b)(i), r to: EPA		r. In accordance milar or identical		
· · · · · · · · · · · · · · · · · · ·			Section -			100	
Amendment - Explain to Resubmission in respon	se to Agency letter	dated		Final printed lab Agancy letter di "Me Too" Appli Other - Explain I	cation.	9	A DEDI
Material This Product Will E Child-Resistant Packaging Yes*	e Packaged In: Unit Packaging Yes		Section - Water Soluble F		1	etal	
	f "Yes" Unit Packaging wgt.	No. per container	No If "Yes" Package wgt	No. per container	GI	estic ess per her (Specify)_	
3. Location of Net Contents In	formation	4. Size(s) Re	tail Container	5.1	On Label D	iractions accompanying	product
6. Manner in Which Label is A	ffixed to Product	Lithog Paper Stend	glued	Other _			
			Section	V			
1: Contact Point (Complete its	ems directly below fo	or identification	on of individual to b	e contacted, if ne	cessary, to proces	s this applica	tion.)
Name			Title		Tele	phone No. (in	nclude Area Code)
I certify that the statement is acknowledge that any both under applicable is	knowingly false or m		all attachments th			te. Rec	s Application eived (Stamped)
2. Signature			3. Title				
4. Typed Name			5. Date	7			97

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any data submitted;
- 8. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other posticide products that are currently registered with the EFA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product,
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

P 4

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber@bed1po1.hcc.com

June 16, 1997

Data Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar

EPA Reg. No. 68451-1

Dear Mr. LaRocca:

Deltamethrin 4% Collar was registered by the Agency in 1996 for use on dogs for control of fleas and ticks. The purpose of this submission is to revise the Deltamethrin 4 % Collar label as required by PR Notice 96-6, as well as to modify the Directions for Use and associated claims. Other label changes being proposed are the revision of the company name and insertion of a Disclaimer statement.

By way of background, Roussel Uclaf Corporation (now AgrEvo Environmental Health (EPA Company No. 432) submitted an application to the U.S. EPA to register Deltamethrin 4% Collar, a product containing 4% deltamethrin. The pending registration was transferred to Roussel Uclaf, S.A., Division Santé Animale (EPA Company No. 68451) on March 23, 1995 On June 5, 1996, the U.S. EPA registered Deltamethrin 4% Collar, to Roussel Uclaf, S.A., Division Santé Animale. Subsequently, the company name of Roussel Uclaf, S.A., Division Santé Animale was changed to Hoechst Roussel Vet S.A.

At the time the Deltamethrin 4% Collar was registered, Hoechst-Roussel Agri-Vet Company (EPA Company No. 54382) was the agent of Roussel

Uclaf, S.A. The name of Hoechst-Roussel Agri-Vet Company was changed to Hoechst Roussel Vet. In regard to this amended registration of Deltamethrin 4% Collar, Hoechst Roussel Vet is acting as the agent of Hoechst Roussel Vet S.A.

Attached you will find 5 copies of the revised label, in which the words to be deleted from the currently registered label are shown with a line drawn through them, while the words added to the label are shown as underlined text. In addition to this label showing the revisions, 5 copies of the label without crossed-out and underlined text are being submitted at this time.

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber Ph.D.

Manager, Product Registration

Attachments

- 1. Amended Registration Application
- 2. Revised label showing deleted and new text
- 3. Revised label

CC

- A. Ahlman w/ attachments
- A. Benitz w/ attachments
- R. Dodemaide w/ attachments
- R. Muser w/ attachments

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

- **←** GUARANTEED WATERPROOF
- ✓ KILLS FLEAS FOR 11 MONTHS
- **✓KILLS TICKS FOR 7 MONTHS**
- *←ODORLESS*
- **FITS DOGS WITH NECKS UP TO 21"**
- **← GUARANTEED OR YOUR MONEY BACK**
- ✓— WETTING WILL NOT IMPAIR THE COLLAR'S EFFECTIVENESS
- **✓MAY BE WORN WITH REGULAR COLLAR**
- **←PATENTED INSECTICIDE RELEASE TECHNOLOGY**

ACTIVE INGREDIENT:

Deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate]

INERT INGREDIENTS

Total

Percentage by Weight

4.0%

96.0% 100.0% 797

_

CAUTION: Do Not Let Children Play With This Collar 5

P4:02

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 1.1 oz

Hoechst Roussel Vet SA Roussel Uclaf, S.A. Division Santé Animale 102 route de Noisy 93235 Romainville, France

page 1 of 3 12 June 1997

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11-Month Flea Killer GUARANTEED 7-Month Tick Killer

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks. 11-month flea-killing power (and 7-month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use this product on cats. Do not use on puppies less_than 3 months of age under 12 weeks. This product is not recommended for use on debilitated, aged, pregnant, medicated, or nursing animals. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterianarian immediately.

FIRST AID STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals.

Applying other pesticides on the dog may not be are not necessary and therefore should not be used on dogs while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, that one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide-release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, Maximum effectiveness may not occur for 2—3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus) and American dog tick (Dermacentor variabilis). Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, This collar should be worn continuously. Reapply a new collar every 6 months.

page 2 of 3 12 June 1997 Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle elose to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Deltamethrin 4% Collar may be used in addition to regular collar a lead or constraint collar. Use only one Deltamethrin 4% flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A.MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VETS.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

ONE SIZE FITS ALL - TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

The Hoechst Name and logo are registered trademarks of Hoechst AG.

© 1997 HRV S.A.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Dr. John J. Lauber Hoechst Roussel Vet Route 202-206 Bedm. P.O. Box 2500 Somerville, NJ 08876-1258

MAR 17 1997

Dear Dr. Lauber

Subject: Condition of Registration- efficacy data

Deltamethrin 3% Collar

EPA Registration Number 68451-1

Deltamethrin 4% Collar

EPA Registration Number 68451-2

Your submission dated August 19, 1996

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the following reasons given below:

1. The data summaries (MRID 44190101) submitted to the Agency are adequate to demonstrate the ability of the active ingredient deltamethrin to kill fleas and ticks on dogs in a preliminary manner when formulated as a collar. However, these data are incomplete for the purpose of supporting specific claims of duration of satisfactory control of fleas and ticks because of the lack of raw data for testing conducted in Arkansas, California and Oklahoma, along with the lack of sufficient detail as to the manner in which the testing was conducted, as required by 95-30(b)1., 3. and 4., 6., 7., 8., 9. and 10., especially 4., 6.1, 6.4, 6.5, 6.7, 7.2, 7.3, 8.1, 8.2, 9.1, 9.2, 9.3, 9.4, 9.5, 9.7, 10.1, 10.2 and 10.4 as elaborated in paragraphs on p. 284.

A copy of the reviews are enclosed.

Sincerely,

George T. LaRocca Product Manager (13) Insecticide-Rodenticide Branch Registration Division (7505C)

Enclosures

EFFICACY REVIEW

DATE: IN 1-13-97 OUT 3- 6-97

FILE OR REG. NO. 68451-1
PETITION OR EXP. PERMIT NO
DATE DIV. RECEIVED
DATE OF SUBMISSION December 19, 1996
DATE SUBMISSION ACCEPTED
TYPE PRODUCT(S): (I,)D, H, F, N, R, S
DATA ACCESSION NO(S). 441901-01;D232552;S516908;Case#034680;AC:571
PRODUCT MGR. NO. <u>13-LaRocca/DeLuise</u>
PRODUCT NAME(S) Deltamethrin 4% Collar
COMPANY NAME Hoechst Roussel Agri-Vet Company
SUBMISSION PURPOSE Provide performance data summaries in support of
claims for control of fleas and ticks on dogs to
establish new use for active chemical ingredient.
CUTIVICAL & PODMULATION (-) 2 (4D 2D) 2 (0 0

CHEMICAL & FORMULATION (s) -α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate 4.00% (impregnated material of unspecified bulk)

CONCLUSIONS & RECOMMENDATIONS The data summaries presented in EPA Accession (MRID) Number 441901-01, having been obtained from standard kennel tests presumably conducted according to a protocol that meets the requirements of § 95-30(b)(11)1. through 10. on pp. 280-4 and the standard of § 95-9(b)(2)(i) on p. 264 of the Product Performance Guidelines, are adequate to demonstrate the ability of the active ingredient deltamethrin to kill fleas and ticks on dogs in a preliminary manner when formulated as a collar. However, these data are incomplete for the purposes of supporting specific claims of duration of satisfactory control of fleas and ticks because of the lack of raw data for testing conducted in Arkansas, California and Oklahoma, along with lack of sufficient detail as to the manner in which testing was conducted, as required by § 95-30(b)1., 3. and 4., 6., 7., 8., 9. and 10., especially 4., 6.1, 6.4, 6.5, 6.7, 7.2, 7.3, 8.1, 8.2, 9.1, 9.2, 9.3, 9.4, 9.5, 9.7, 10.1, 10.2 and 10.4 as elaborated in paragraphs on p. 284. While Reference 1 comes closer to meeting these requirements, References 2 and 3 are only summary and abstract, respectively. References 4 through 6 are for kennel tests conducted in Europe, and while Reference 4 (to be continued)

actually gives more details as to these requirements than do the latter two reports from the U. S., it fails to identify all the formulations in the test as to active ingredient as required by § 95-30(b)2.5; References 5 and 6 are nothing more than conclusions and lack sufficient detail in many of the categories previously mentioned above. Furthermore, since the submission was not accompanied by either labeling or CSF, it is not possible to relate the conclusions and results of any of these references to the support of specific claims of duration of satisfactory control or range of flea and tick species against which the collar is found effective. Mention is made at the end of Reference 1 of original data found in the Appendix, pp. A41-A124, and of quality assurance unit inspections and the final report following the Appendix as pp. QUA1-QUA9. The submission of this information along with specific information meeting above requirements with respect to References 2 through 6 is necessary for proper review of the effectiveness of the collar, along with labeling as to the claims which these data are believed to satisfactorily support.

OBJ Vern L. McFarland, IRB

Hoechst Roussel Vet

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber1@bed1po1.hcc.com

441901-00

August 19, 1996

Mr. George T. LaRocca
Office of Pesticide Programs
Document Processing Desk (APPL)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. LaRocca:

Subject:

Deltamethrin 3 and 4% Collars

EPA Registration Nos. 68451-1 and 2

Notice of Registration Dated June 5, 1996

As a condition of the registrations of the Deltamethrin 3 and 4% Collars, we committed to submit to the Agency within three months of the date of the Registration Notice, a summary of efficacy data demonstrating control of fleas and ticks. Attached you will find three copies of the report: "Deltamethrin Dog Collars - Efficacy Studies". In this report, the results of several efficacy studies with the 3 and 4% collars are presented.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Agent for Roussel Uclaf, S.A., Division Santé Animale

Attachment: 3 copies of the report "Deltamethrin Dog Collars - Efficacy Studies".

Hoechst Roussel Vet

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber1@bed1po1.hcc.com

December 19, 1996

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Dear Sir/Madam:

Subject:

Deltamethrin 3 and 4% Collars

EPA Registration Nos. 68451-1 and 2

Hoechst Roussel Vet submission dated August 19, 1996 EPA Report of Analysis for Compliance with 86-5 dated

September 4, 1996

On December 17, I received the "Report of Analysis for Compliance with PR Notice 86-5" (copy enclosed). The notice was dated September 4, 1996. I don't know why the notice was delayed in reaching me.

The notice indicated that our statement of no data confidentiality claims is contradicted by the markings on the first page of Reference 4. I have corrected this and am enclosing 3 copies of this corrected page. Please remove the old page from the copies previously submitted and substitute the new page.

Thank you in advance for your help.

Sincerely yours,

John J. Lauber Ph.D.

Manager, Product Registration

Enclosures 961218b

1665506323

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA Reg. Office of Pesticide Programs

Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460

NOTICE OF PESTICIDE:

x Registration Reregistration

(under PIFRA, as amended)

Number

Date of Iscuance:

68451-1

" K JUN 1996

Term of Issuance:

Unconditional

Name of Pesticide Product:

Deltamethrin 4% Collar

Name and Address of Registrant (include ZIP Code);

Hoechst-Roussel Agri-Vet Company

Route 202-206 Bedm. 1

PO Box 2500

Somerville, NJ 08876-1258

Note: Changes in tabeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commercs. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B).

- Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1".
- 2. We note that in your May 14, 1996 letter you agreed to submit efficacy data supporting label claims within 3 months of the date of this notice.
- 3. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

George T. LaRocca Product Manager (13) Insecticide-Rodenticide Branch Registration Division (H7505C)

		acc. 1.4	CONCURREN	CES	7			
SYMBOL	signature of Approving	orrient.						
SURNAME	Helen		***************************************	***************************************		***************************************	**********	******
DATE	A Form 8570-6			***************************************		CALL Y CREATE THE PARTY HAD		
FPA For	m 1320-14 (1/00)		u versioner			OFFIC	1A1 991 E	CORY

Printed on Recycled Paper

NOTICE OF PESTICIDE: X Registration Reregistration Reregistration Reregistration Respective to the label of content of the product in section prior to the label in content of any correspondence on this product under the Poster label in section of a product under the Poster label in section of a product under the Poster label in section of a product under the Poster label in section of a product under this vac is not regarded as permanently acceptable. Registration of a product under this vac is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency distribute that a product is unconditionally registered to the registration as product is unconditionally registered to the product under this vac is now registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency distribute that a product is unconditionally registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation. A standed copy of the label is faclosed for your records.			
Name and Address of Registrant (include ZIP Code): Hoechst-Roussel Agri-Vet Company Route 202-206 Bedm. 1 PO Box 2500 Somerville, NJ 08876-1258 Recent Changes in Labeling diffacting in substance from that secreted by connection with this registration must be substituted to and accopated by the Registration Division prior to use of the label in commerce. To any correspondence on this product always rejervable to the above MPA registration number. On the basis of information furnished by the registrant, the slope named posticide is hereby registered/recregistered under the Federal Insecticide, Fungicipie and Rodenticide Act. Registration is in no way to be constructly an endorsement for recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his notion, may at any time suspend or cancel the registration of a product under this Act is not to be construct as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3 (c) (5). Once a resolucide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. (e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the	Office of Pesticide Programs Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460 NOTICE OF PESTICIDE:	Number	Date of Issuance:
Name and Address of Registrant (include ZIP Code): Hoechst-Roussel Agri-Vet Company Route 202-206 Bedm. 1 PO Box 2500 Somerville, NJ 08876-1258 Reta. Charges in Labeling differing in substance from that secepted by connection with this registration must be substituted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number. On the basis of information furnished by the registrant, the slope named posticide is hereby registered/recigiatered under the Federal Insecticide, Fungicies and Rodenticide Ast any time suspend or cancel the registration of a pesticide in accordance with the Administrator, on his notion, may at any time suspend or cancel the registration of a product under the Federal insection to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3 (c) (5). Once a resolucide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. (e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the		TARRA CENTERS	
Name and Address of Registrant (include ZIP Code): Hoechst-Roussel Agri-Vet Company Route 202-206 Bedm. 1 PO Box 2500 Somerville, NJ 08876-1258 Rete: Changes in labeling differing in subseases from that accepted by connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above BPA registration maker. On the basis of information furnished by the registrant, the slope named posticide is hereby registered/reregistered under the Federal Insecticide, Fungiciae and Rodenticide Act. Registration is in no way to be construct as an endorsement of recommendation of this product by the Agency, in order to protect health and the environment. The Administrator, on his motion, say at any time suspend or cancel the registration of a product under this Act is not to be construct as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3 (c) (5). Once a restricted is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. (e), Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the	(under PIFRA, as amended)	Uncondit	ional
Name and Address of Registrant (include ZIP Code): Hoechst-Roussel Agri-Vet Company Route 202-206 Bedm. 1 PO Box 2500 Somerville, NJ 08876-1258 Note: Changes in labeling differing in substance from that accepted is connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in comserce. In any correspondence on this product always refer to the above BPA registration on the basis of information furnished by the registrant, the above named posticide is hereby registered/reregistered under the Federic Inserticide. Punylocis and Rodenticide Act. Registration is in no way to be construct as an endorsement or recommendation of this product by the Agency. The order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a product where this act is not to be constructed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3 (c) (5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the		Name of Pesti	cide Froduct:
Name and Address of Registrant (include ZIF Code): Hoechst-Roussel Agri-Vet Company Route 202-206 Bedm. 1 PO Box 2500 Somerville, NJ 08876-1258 Robe: Changes in labeling differing in substance from that accepted is connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product saves refer to the above PRF registration musture. On the basis of information furnished by the registrant, the shope named posticide is hereby registered/reregistered under the Federal Insecticide, Fungicipie and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or not be registered to protect health and the environment, the Administrator, on his motion, may at any time suspend or with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3 (c) (5). Once a passicide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e), Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the		Deltamet	brin 4%
Hoechst-Roussel Agri-Vet Company Route 202-206 Bedm. 1 PO Box 2500 Somerville, NJ 08876-1258 Reta: Changes in labeling differing in substance from that accepted in commection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above PRA registration number. On the basis of information furnished by the registrant, the above named posticide is hereby registered/reregistered under the Federal Insecticide, Fungiciae and Rodenticide Act. Registration is in no way to be construed as an endorsement for recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in advordance with the Act. The acceptance of any name in connection with the registration of a predict under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been/covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3 (c) (5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e), Your release for shipment of the product constitutes acceptance of these conditions. A standard copy of the		Collar/	
Route 202-206 Bedm. 1 PO Box 2500 Somerville, NJ 08876-1258 Research angse in labeling differing in substance from that accepted by commection with this registration must be substituted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always retar to the above IPA registration number. On the basis of information furnished by the registrant, the above named pseticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a presticide in advances with the Act. The acceptance of any name in connection with the registration of a presticide in advances with the Act. The acceptance of any name in connection with the registration of a presticide in accordance with filter product is unconditionally registered in accordance with FIFRA sec. 3 (c) (5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the		/	
PO Box 2500 Somerville, NJ 08876-1258 Rota: Changes in labeling differing in substance from that accepted in commection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above BPA registration number. On the basis of information furnished by the registrant, the above named pesticide is hereby registered/exergistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a product under this act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been/covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3 (c) (5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 5(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the			
Somerville, NJ 08876-1258 Note: Charges in labeling differing in substance from that accepted it connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above BFA registration number. On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Theodore and Rodenticide Act. Registration is in no way to be construct as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is now to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3 (c) (5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6 (e). Your release for shipment of the product constitutes acceptance of these conditions. A statuped copy of the	가면 및 성계하게 하는 이번 성격하는 문자인 및 보고 이 경험 되는 이 생각이 하다면 하는데 보고 있다.		
be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always resist to the above EPA registration number. On the basis of information furnished by the registrant, the above named posticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a posticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of posticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3)(c)(2)(B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stanped copy of the		/	
registered/reregistered under the Federal Insecticide, Fungicial and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in advordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been/covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3)(c)(2)(B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the	be submitted to and accepted by the Registration Division prior to	use of the label in c	his registration must ommerce. In any
In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3)(c)(2)(B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the	On the basis of information furnished by the registrant, the above registered/reregistered under the Federal Insecticide, Fungicide and	named pesticide is he d Rodenticide Act.	reby
FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3)(c)(2)(B). 1. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the	In order to protect health and the environment, the Administrator, cancel the registration of a pesticide in accordance with the Act.	on his motion, may at The acceptance of an	any time suspend or y name in connection
Registration Number to read, "EPA Reg. No. 68451-1". 2. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the	FIFRA sec. 3(c)(5). Once a pesticide is is not regarded as permanently acceptable eliminate the need for continual reassess the Agency determines that, at any time, required to maintain in effect an existin Agency will require submission of such determines.	registered, e. Registrat sment of pest additional d ng registrati	however, it ion does not icides. If ata are on, the
for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the	1. Make the following label change: Registration Number to read, "EPA Reg. No	Revise the 68451-1".	EPA
	for the record. If these conditions are registration will be subject to cancellat FIFRA sec. (e). Your release for shipme constitutes acceptance of these condition	not complied ion in accor ent of the pr	with, the dance with oduct
George A. LaRocca	George A. LaRocca		1
Product Manager (13)			1
Insecticide-Rodenticide Branch Registration Division (H7505C)			1

EPA Form 8570-6

Signature of Approving Official:

Kelent

Date:

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

- **GUARANTEED WATERPROOF**
- **KILLS FLEAS FOR 11 MONTHS**
- **KILLS TICKS FOR 7 MONTHS**
- **ODORLESS**
- FITS DOGS WITH NECKS UP TO 21"
- **GUARANTEED OR YOUR MONEY BACK**
- WETTING WILL NOT IMPAIR THE COLLAR'S **EFFECTIVENESS**
- MAY BE WORN WITH REGULAR COLLAR
- PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENT:

Deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate]

INERT INGREDIENTS

Total

Percentage by Weight

4.0%

96.0%

100.0%

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 1.1 oz

ACCEPTED with COMMENTS in EPA Letter Dated

Roussel Uclaf, S.A. Division Santé Animale 102 route de Noisy

5 JUN 1996

93235 Romainville, France Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 8451-

May 14, 1996

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11-Month Flea Killer GUARANTEED 7-Month Tick Killer

Deltamethrin 4% Collar provides full season, 11-month flea-killing power (and 7-month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. **Do not use this product on cats.** Do not use on puppies less than 3 months of age.

This product is not recommended for use on debilitated, aged, pregnant, medicated, or nursing animals. Consult a veterinarian before using.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2 - 3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus) and American dog tick (Dermacentor variabilis). Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL - TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

May 14, 1996

Hoechst-Roussel Agri-Vet Company

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber1@bed1po1.hcc.com

May 14, 1996

Mr. George T. LaRocca
Office of Pesticide Programs
Document Processing Desk (APPL)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

deltam. Thru

dog collar

Dear Mr. LaRocca:

Subject:

Registration Application **Deltamethrin 4% Collar**EPA File Symbol 68451-R

Your Letter Dated May 2, 1996

You indicated in your letter that the subject product is acceptable for registration provided that we agree in writing to the following:

1. Submit a summary of efficacy data demonstrating control of fleas and ticks that are consistent with labeling claims. This information to be submitted to the Agency within 3 months of the date of the registration notice

2. Make labeling changes

We agree to supply to the Agency a summary of efficacy data demensions control of fleas and ticks within 3 months of the date on the Notice of Registration.

I am enclosing three copies of final printed labeling in which I have incorporated all the changes that you requested.

I believe all is in order and that the Notice of Registration can be issued. Thank you in advance for receipt of the Notice.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Biologics & Pesticide Product Registration Agent for Roussel Uclaf, S.A., Division Santé Animale

Enclosure

cc by e-mail

- L. Ahlman
- A. Benitz
- C. Chieze
- R. Dodemaide
- A. Donoghue
- C. Focheux
- D. Frey

PY Kravtchenko

R. Muser

JP Scheid

96 05 08b

166 5494967

0 2 MAY 1986

Mr. Jack Lauber Roussel Uclaf Hoechst-roussel Agri-Vet Co. Route 202-2026 PO Box 2500, Bedm. 31 Somerville, NJ 08876-1258

Dear Mr. Lauber:

Subject: Registration Application

Deltamethrin 4% Collar EPA File Symbol 68451-R

Your Letter Dated August 11, 1993

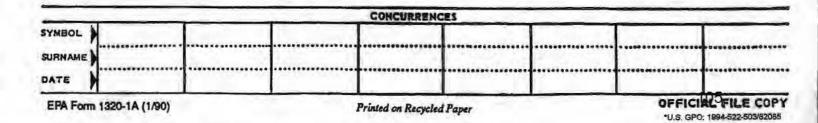
The product referenced above will be acceptable for registration under FIFRA sec. 3(c)(7)(A) and (B) provided that you agree in writing to:

1. Submit a summary of your efficacy data demonstrating control of fleas and ticks that are consistent with labeling claims. We request this information be submitted to the Agency within 3 months of the date of this registration notice.

And make the following labeling changes:

2. Revise your Statement of Practical Treatment as follows: IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. IF ON SKIN: Wash with plenty of soap and water. Get medical attention. IF ON EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Refer to your copy of the May 16, 1995 Precautionary Review Section review for complete information on your product's acute toxicity profile.



- 3. Revise the heading so it reads Hazards to Humans and Domestic Animals. Also, revise the statements so that they read "Harmful if swallowed or absorbed, through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Do not use this product on cats (note: this sentence should appear in bold). Do not use on puppies less than 3 months of age.
- 4. Revise the statements regarding sick or convalescing dogs to read as follows: "This product is not recommended for use on debilitated, aged, pregnant, medicated, or pregnant animals. Consult a veterinarian before using."
- 5. Delete the statement "Initial use of collar is to be in conjunction with dip or dust." Your product should not depend on other products for efficacy. If this collar is part of a flea control program you should list specific (active ingredient) products to be used. Depending on the type of product(s) chosen and the rate of application we may require additional domestic animal safety and/or efficacy data.
- 6. Delete "..and deer tick (Ixodes scapularis) which may carry Lyme disease." This is a public health claim which requires the submission of supportive efficacy data.
- 7. Delete the claims "new molecule first collar formulated with a pyrethroid" and "one of the longest lasting flea and tick killers...etc." There are other pyrethroid collars registered. Also words or phrases implying that a product possesses unique characteristics because of its composition are not acceptable. You may use the word new or new formulation for a period of six months following the notice of registration.
- 8. Under the signal word we recommend revise "Keep out of the reach of children" to "Do not let children play with this collar."
- Singularize the term Active Ingredients. Your product contains only one active ingredient.
- 10. Delete the asterisk and have the chemical name follow the common name in the ingredient statement. Deltamethrin was registered in the U. S. two years ago and is not considered a commonly recognized name in the U. S.

You will submit three copies of your final printed labeling before you release the product for shipment.

The "Notice of Registration" will be issued when you have agreed in writing to the conditions stated above and submitted corrected labels.

THIS LETTER DOES NOT CONSTITUTE REGISTRATION, AND THE PRODUCT MAY NOT BE LAWFULLY MARKETED UNTIL IT IS REGISTERED.

Please respond within 75 days from the date of this letter stating your intentions to comply with the information/data requests cited above. If no resubmission is received during the 75-day period, the application will be administratively withdrawn.

Sincerely,

George T. LaRocca Product Manager 13 Insecticide-Rodenticide Branch Registration Division (7505C) Deschmusion-514

* 8-1-9

Hoechst-Roussel Agri-Vet Company

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258 Telex 833-449 Cable Hoechstus, Somerville, NJ

Telephone (908) 231-3426 Fax (908) 231-4462

August 22, 1995

Mr. George T. LaRocca (PM 13)
Office of Pesticide Programs (H7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Dog Collar EPA File Symbol 68451-R (previously EPA File Symbol 432-TTO)

Dear Mr. LaRocca:

As the authorized representative and principal contact of Roussel Uclaf, S.A., Division Santé Animale, I am responding to the questions raised in a Product Chemistry Review concerning the Deltamethrin 4% Dog Collar.

By way of background, on August 11, 1993, Roussel Uclaf Corporation (now AgrEvo Environmental Health) submitted a Registration Application (plus supporting information) for the registration of Deltamethrin 4% Dog Collar. The pending registration was assigned EPA File Symbol 432-TTO. On March 23, 1995, the pending registration was transferred to Roussel Uclaf, S.A., Division Santé Animale. The pending registration was assigned EPA File Symbol 68451-R. On April 13, 1995, Mr. John Hebert of your staff provided me with the Product Chemistry Review dated December 29,...

The Product Chemistry Review raised the following requirements:

- 1. Revise the label ingredient statement
- 2. Revise the Confidential Statement of Formula by correcting the CAS # for deltamethrin

Product ingredient source information may be entitled to confidential treatment

- 3. Revise the manufacturing process relative to temperature (Fahrenheit or Centigrade).
- 4. Provide information concerning Corrosion Characteristics, Storage Stability, and Flammability
- 5. Provide additional information concerning three inert ingredients previously not approved for use in dog collars

Our response to these requirements is as follows;

1. Revision of the Label Ingredient Statement

Attached you will find a revised label which positions the ingredient statement as specified in the product chemistry review. The name and address of the registrant was also revised because of the transfer of the pending registration.

2. Revision of the Confidential Statement of Formula

While not stated in the product chemistry review, the Confidential Statement of Formula needs to be revised to reflect that the Deltamethrin Technical used in making the Deltamethrin 4% Dog Collar is active as indicated on the Confidential Statement of Formula dated August 11, 1993. Attached you will find a revised Confidential Statement of Formula revised to reflect the In addition, I have corrected the CAS # for deltamethrin and revised the amounts in Sections 13 and 14 to reflect the very slight change in introducing a Deltamethrin Technical of lower concentration, and its slight effect on the concentration of solvent used in making the product. Also, I have revised Sections 1, 2, and 6 to reflect the new registrant Roussel Uclaf, S.A., Division Santé Animale.

3. Manufacturing Process Revision

On page 6, CONFIDENTIAL ATTACHMENT, Volume 1 of the August 11; 1993 submission concerning the Manufacturing Process, all temperatures shown should be ° F. A corrected page is attached.

4. Corrosion Characteristics, Storage Stability, and Flammability

With our submission dated August 21, 1995, we submitted a report which will satisfy the Product Chemistry requirements for Corrosion Characteristics and Storage Stability.

Concerning flammability, the Agency states in its Guidelines Ref. 63-15 (40 CFR 158.190) that flammability data is "required if the product contains combustible liquids". Deltamethrin 4% Dog Collar does not contain any liquid combustible ingredients. It is not flammable and consequently, a flammability test was not performed.

5. Inert Ingredients Not Approved for Use in Dog Collars

Information concerning the three inert ingredients previously not approved for use in dog collars has been submitted to the Agency under separate cover.

If you have any questions or require additional information, please do not hesitate to contact me. Thank you in advance for your help concerning the registration of Deltamethrin 4% Dog Collar.

Sincerely yours,

John J. Lauber Ph.D.

Manager, Product Registration

Attachments

Revised label (5 copies), revised CSF, revised p.6 of CONFIDENTIAL ATTACHMENT pertaining to manufacturing,

CC

L. Ahlman

C. Chieze

A. R. Donoghue

D. Frey

P.-Y. Kravtchenko

R. K. Muser

L. Poly

J. P. Scheid

M. Trausinger

/95 08 17c

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

	✓	GUARANTEED WATER PROOF
	✓	KILLS FLEAS FOR 11 MONTHS
	✓	KILLS TICKS FOR 7 MONTHS
ŝ	√	NEW MOLECULE - FIRST COLLAR FORMULATED WITH PYRETHROID
	✓	ODORLESS
	. ✓	FITS DOGS WITH NECKS UP TO 21"
*	✓	GUARANTEED OR YOUR MONEY BACK
	✓	ONE OF THE LONGEST LASTING FLEA
		& TICK KILLERS AVAILABLE FOR USE ON DOGS
	✓	WETTING WILL NOT IMPAIR COLLARS EFFECTIVENESS
	✓	MAY BE WORN WITH REGULAR COLLAR
	✓.	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENT: Deltamethrin* INERT INGREDIENTS Total

Percent by Weight 4.0% 96.0% 100.0%

 (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar
NET WT. 1.1 oz

EPA Reg. No. 68451
EPA Est. No.

Roussel Uclaf, S.A.
Division Santé Animale
102 route de Noisy
93235 Romainville, France

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

NOV 1 6 1993

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT:

EPA Id# 000432-TTI. Deltamethrin: Review of a domestic animal safety study with the product

"Deltamethrin 3% Collar".

TOX CHEM No.: 463B PC No.: 097805

Barcode No.: D194602 Submission No A S446520

FROM:

John Doherty

John Doherty John Section IV, Toxicology Branch I Health Effects Division (7509C)

TO:

George LaRocca/John Hebert

Product Manager #13

Registration Division (7505C)

THROUGH:

Marion Copley, DVM, Section Head

Section IV, Toxicology Branch I

Health Effects Division (7509C)

CONCLUSION

The domestic animal safety study with the product Deltamethrin 3% Collar was reviewed and determined to be ACCEPTABLE. No reactions to treatment were noted when one collar (4% active ingredient worn for six months), four collars (3% active ingredient worn for three months, or 4% active ingredient worn for six months) were worn.

The product has been demonstrated to be safe for adult dogs. If the registrant wishes to register the product for use on dogs less then 3 months of age an additional study using puppies of defined age will have to be presented.

II. Action Requested

The Roussel Uclaf Company (refer to letter from Sharon M. Johnson dated July 9, 1993) has submitted a domestic animal safety study (MRID No.: 428890-06) with dogs to support the registration of the product Deltamethrin 3% Collar. The study was reviewed and the following comments apply.

III. Toxicology Branch Comments

- 1. The study was determined to be ACCEPTABLE and to demonstrate the safety of the product to <u>adult</u> (see item 2 below) dogs. The study demonstrated that there were no effects of wearing 3 or 4 collars equivalent to 3 or 4 times the recommended usage rate for up to six months. Refer to the DER attached.
- 2. The age of the test dogs was not specified in the study report. Therefore, the product is considered to have been demonstrated to be safe for use on <u>adult</u> dogs (greater than 3 months of age). The product label should thus include in the precautionary statement <u>for use on dogs of greater than 3 months of age only.</u> Or do not use on puppies less than 3 months of age. [Note: This precautionary statment is already included on the draft label dated July 20, 1993.]

If the registrant wants to use the product on puppies less than 3 months of age, the registrant will have to provide the exact ages of the dogs used in the existing study and demonstrate that treatment was initiated at a specified age less than 3 months.

Alternatively, the registrant will have to submit a second study in which the treated puppies are of a defined age. For example, if one month old puppies are treated, and the study demonstrates the 3 fold safety factor in which no reactions are noted, the product label can be amended to include for use of puppies greater than one month of age. If this study is conducted, the puppies should not have to treated for more than two weeks and the ChE and AChE assays should not have to be included.

IV. Studies Reviewed

Study Identification	Material	MRID No.:	Results	Classification
86-1. Domestic animal safety study-dogs. Hazleton.# HWA 2623-103. April 11, 1993	3% and 4% deltamethri n containing collars from lots 1103 (3%) and 1104 (4%).	428890-06	No reactions to wearing collars at 3X (for three months) and 1X and 4X (for six months). Mongrel purpose bred dogs. Control (4 collars without delta-methrin), deltamethrin treated collars: 4%, 1 collar for 6 months; 3%, 4 collars for three months and 4%, 4 collars for six months.	ACCEPTABLE. The study satisfies the requirement for a domestic animal safety study for adult dogs. An additional study may be required to support the use of this product on puppies less than three months of age.

[86-1. Dogs 4% collars/1993]

Reviewed by: John Doherty June 11/15/93

Section IV, Toxicology Branch I (7509C)

Secondary reviewer: Marion Copley, DVM Mawa Wolf 1/12/ Section IV, Toxicology Branch I (7509C)

DATA EVALUATION REPORT

STUDY TYPE: 86-1. Domestic animal safety study (6 month-dogs)

MRID NO.: 428890-06.

TOX. CHEM. NO.: 463B

PC No.: 097805

TEST MATERIAL: 3% (from lot No.: 1103) and 4% (from lot 1104) deltamethrin fortified dog collars.

STUDY NUMBER (S): HWA 2623-103 and RBT No.: 91-135.

SPONSOR: Roussel Bio Corporation, Lincoln Park, New Jersey

TESTING FACILITY: Hazleton Washington, Inc.

TITLE OF REPORT: "6-Month Deltamethrin Flea and Tick Collar Safety Study in Dogs"

AUTHOR(S): Dan W. Dalgard, D.V.M.

REPORT ISSUED: April 11, 1993

STUDY DATES (in life): Initiation: November 27, 1991, Termination June 29, 1992.

CONCLUSIONS:

No reactions to wearing collars at 3X (for three months) and 1X and 4X (for six months).

Mongrel purpose bred dogs. Control (4 collars without deltamethrin), deltamethrin treated collars: 4%, 1 collar for 6 months; 3%, 4 collars for three months and 4%, 4 collars for six months.

Classification: ACCEPTABLE. The study satisfies the requirement for a domestic animal safety study for adult dogs. An additional study may be required to support the use of this product on puppies less than three months of age.

Quality Assurance Statement: Provided. Good Laboratory Practice Statement: Provided. All dogs survived the experiment and no treatment related findings were noted.

2. Body weight and feed consumption.

Body weight and feed consumption were reportedly assessed weekly. The study author maintains that there were no compound related effects on these parameters.

TB-I considers that the body weight and feed consumption data showed variations for which interpretation was confounded by the fact that the dogs were mongrels and of different sizes and there were only four dogs/sex/treatment group. Inspection of the growth curve for females (refer to Figure 3, photocopied from the study report attached) supports the conclusion of the study author. The male group wearing only one collar had a higher rate of growth than the other dogs. The report, however, asserts that this is related to the dogs being mixed and mongrels. Since the dogs wearing four collars (with either 3 or 4% deltamethrin) did not also show indications of similar increased weight gain, TB-I concurs that the weight gain pattern for the group wearing only one collar was not affected by the presence of the deltamethrin in the collar.

There also appeared to be an increase in feed consumption in the dogs (both sexes) wearing 4 collars with 4% deltamethrin in the later weeks of the study (refer to Figure 3 photocopied from the study report attached). TB-I does not consider that the apparent increase is conclusively related to treatment.

3. Clinical Hematology and Biochemistry

Samples of blood were taken from the jugular vein from fasted dogs on days -7, -6, -3, 2, 4, 8, 15, 22, 29, 54 and 89 and 180. for plasma ChE and RBC AChE. Blood samples for days -13, 25, 51 and 86 and 177 were also taken for hematology and serum chemistry.

A. <u>Hematology</u>. The following hematology parameters were reportedly investigated.

cell morphology corrected leukocyte count erythrocyte count erythrocyte sedimentation rate hematocrit hemoglobin leucocyte count leucocyte differential platelet

No consistent compound related effects were noted on any of these parameters.

REVIEW

Experimental Constants:

Test Material: Deltamethrin impregnated dog collars containing 3% (from lot #1103) or 4% (from lot #1104) and placebo collars without deltamethrin (lot #110C) obtained from the Roussel Uclaf Company.

<u>Test System:</u> Purpose bred mongrel dogs with both short and long hair were obtained from the Hazleton Research Products, Inc. Cumberland, Virginia. The exact age of the dogs at initiation of dosing (age of application of the collars) was not referenced in the report.

Basic Experimental Design

Four groups of 4/sex dogs which consisted of a control (placebo collar), low dose (usage rate or one collar of 4% deltamethrin, actually slightly greater than the usage rate of a 3% collar), mid dose (4 collars of 3% deltamethrin) and high dose (4 collars of 4% deltamethrin). The dogs were scheduled to wear their collars for six months. After three months, the mid dose group was terminated because there were no reactions noted in any group. The control, low and high dose groups continued for the scheduled six months.

Analytical Chemistry

- 1. Release rates of deltamethrin from the collars. Sections of the 3% and 4% collars were removed and analyzed for deltamethrin at pretest, at three and six months to determine the rate of release from the matrix. The Analytical report is in Appendix 11. In summary the analytical data were shown to have release rates 120 ug/collar/day for the 3% collar at the 3 month interval. The 4% collars were shown to have release rates of 40 and 251 ug/collar/day at the 3 and 6 month intervals.
- 2. Blood levels of deltamethrin. The blood was sampled from the dogs wearing only one collar on days 25, 51, 86 and 177 and analyzed for deltamethrin content. The limit of assay was said to be 5 ng/ml. No detectable deltamethrin was evident at days 25, 51 and 86. Although some evidence of < 5 ng/ml was noted for three dogs at day 177, the study report did not consider these readings actual (referring to them as incidental). TB-I concurs and does not consider that wearing a single collar resulted in significant levels of deltamethrin in the blood.

Assessments and Results

1. Survival and clinical signs.

The dogs were reportedly examined twice daily for mortality and once daily for behavioral reactions. In addition, a staff veterinarian examined the dogs on days 1, 8, 26, 88 and 179 (in addition to two pretreatment examinations) for dermatological and clinical evaluations including heart and respiratory rate and body temperature recordings.

B. Serum Chemistry

alanine aminotransferase (ALT albumin albumin/globulin ratio alkaline phosphatase aspartate aminotransferase blood urea nitrogen calcium chloride creatine kinase

creatinine
globulin
glucose
inorganic phosphorous
potassium
sodium
total bilirubin
total protein
RBC ACh F
Plasma Ch F

No consistent compound related effects were noted on any of these parameters.

There were some instances on <u>increased</u> RBC AChE (including in the preapplication period) and plasma ChE. Increases in the activity of these enzymes is not a recognized toxicity response. Since there was no inhibition of these enzymes and the increases were not related to the quantity of the collars worn, it is concluded that the treatment did not affect these enzymes. More poer, ChE and AChE are not recognized as being inhibited by pyrethroids such as deltamethrin.

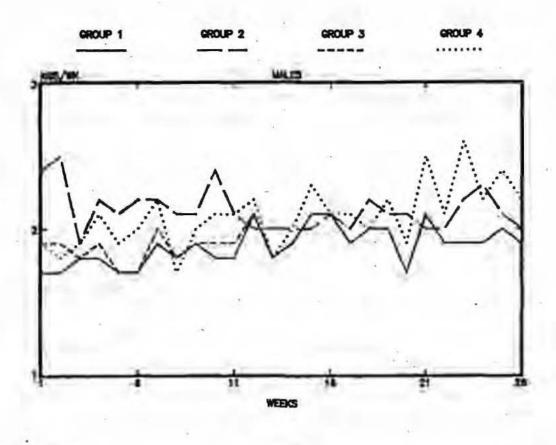
No necropsy was performed and is not considered necessary.

CONCLUSION (Study). The study is considered ACCEPTABLE. No additional domestic animal safety studies are required at this time. The study supports the following "one liner":

No reactions to wearing collars at 3X (for three months) and 1X and 4X (for six months).

Mongrel purpose bred dogs. Control (4 collars without deltamethrin), deltamethrin treated collars: 4%, 1 collar for 6 months; 3%, 4 collars for three months and 4%, 4 collars for six months.

FIGURE 3 - MEAN FOOD CONSUMPTION



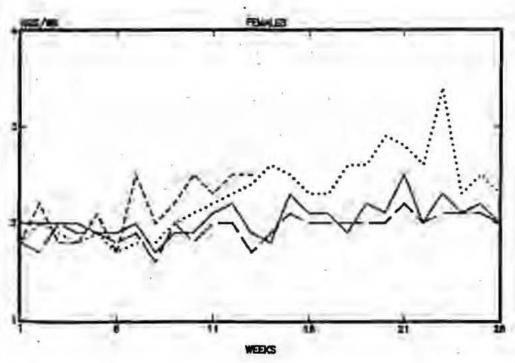
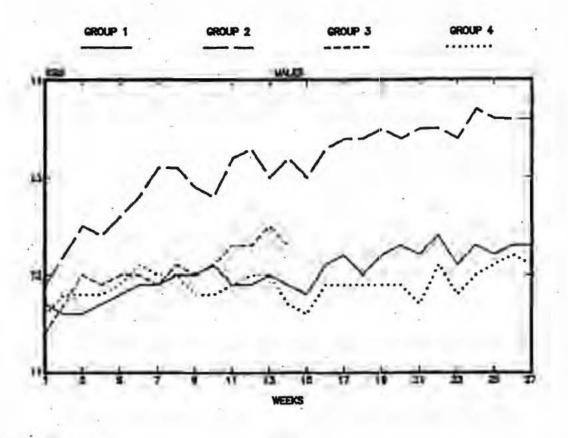
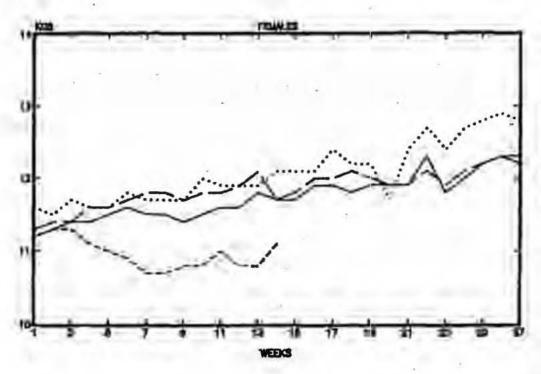


FIGURE 2 - MEAN BODY WEIGHTS







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

		00	(7 00)
OPTIONAL	FORM	99	(7-90)

AX TRANSMITTA

GENERAL SERVICES ADMINISTRATION

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA File Symbols: 432-TTI / 432-TTO

From:

Mark J. Perry, Biologist

Precautionary Review Section Registration Support Branch Registration Division (7505W)

To:

G. LaRocca, PM-13 / J. Hebert

Registration Division (7505C)

Applicant: Roussel-Uclaf Corp.

95 Chestnut Ridge Road Montvale, NJ 07645

FORMULATION FROM LABEL:

Active Ingredient(s): Deltamethrin 4.0

Inert Ingredient(s): 96.0

Total:

100%

BACKGROUND

Roussel-Uclaf Corporation submitted acute oral, acute dermal, eye irritation, dermal irritation and dermal sensitization studies, as well as an acute inhalation waiver request for review. The studies were performed with the Deltamethrin 4% Collar (EPA File Symbol 432-TTO); the registrant has requested that these studies also support registration of the Deltamethrin 3% Collar (EPA File Symbol 432-TTI). Both products are insecticidal dog collars containing deltamethrin as the only active ingredient.

The performing laboratory is Stillmeadow, Inc., and the assigned MRID numbers are 428890-01 through 428890-05.

RECOMMENDATIONS

- 1. Acute Oral; Category III / Acceptable
- 2. Acute Dermal; Category III / Acceptable

An impermeable material, such as plastic, is recommended for semi-occlusion in dermal toxicity studies.

3. Acute Inhalation; Waiver Accepted

PRS does not believe that this product poses a significant inhalation hazard.

- 4. Eye Irritation; Category III / Acceptable
- 5. Dermal Irritation; Category IV / Acceptable
- 6. Dermal Sensitization; Non-sensitizer / Acceptable

The study report failed to specify that the concentration selected for induction and challenge was the highest achievable concentration after moistening.

More detailed positive control data was obtained from the performing laboratory (attached). Although the positive control study employed the same concentration for induction and challenge, the data does demonstrate a sensitizing response.

LABELING

- 1. The recommended signal word is "caution."
- 2. The recommended statements of practical treatment are as follows:

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention. IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

3. The recommended precautionary statements are as follows:

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

4. The signal word should appear on a separate line just below the child hazard warning ("Keep out of reach...").

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (81-1)

Reviewer: M. Perry

Report Date:3/11/92

Report No.:8668-92

Product Manager: 13 MRID No.: 428890-01

Testing Facility: Stillmeadow

Author(s): J. Kuhn

Species: Rat

Age: Young adult Weight: 175-243 g Source: Harlan SD

Test Material: Deltamethrin 4% Collar (reduced)
Quality Assurance (40 CFR 160.12): Present

Conclusion:

1. LD₅₀ (mg/kg): Males= 4218 mg/kg

Females= 3600 mg/kg
Combined= 3920 mg/kg

2. The estimated LD_{50} is 3920 mg/kg.

3. Tox. Category: III Classification: Acceptable

Deviations from 81-1: None

Results:

	(Number	Killed/Number	Tested)
Dosage mg/kg	Males	Females	Combined
2500	0/5	0/5	0/10
3500	1/5	2/5	3/10
5050	4/5	5/5	9/10

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (81-2)

Reviewer: M. Perry

Report Date: 2/21/92

Report No.:8669-92

Product Manager: 13

MRID No.: 428890-02

Testing Laboratory: Stillmeadow

Author(s): J. Kuhn Species: Rabbit

> Weight: 2.0-2.6 kg Source: Ray Nichols

Test Material: Deltamethrin 4% Collar (reduced)

Quality Assurance (40 CFR 160.12): Present

Summary:

LC₅₀ (mg/kg): Males= --

Females = --

Combined 2020 mg/kg

- The estimated LD₅₀ is greater than 2020 mg/kg.
- Tox. Category: III Classification: Acceptable

Deviation From 81-2: See recommendations

Results:

Reported Mortality

223710	(NUMBER KILLED/NUMBER TESTED)			
DOSAGE mg/kg	Males	Females	Combined	
2020	0/5	0/5	0/10	
			6	

DATA REVIEW FOR SKIN IRRITATION TESTING (81-5)

Reviewer: M. Perry

Report Date: 2/11/92

Report No.:8671-92

Product Manager: 13

MRID No.:428890-04

Testing Laboratory: Stillmeadow

Author(s): J. Kuhn Species: Rabbit

Age: Young adult

Sex:3 male, 3 female

Weight: --

Dosage: 0.5 q

Test Material: Deltamethrin 4% Collar (reduced)

Quality Assurance (40 CFR 160.12): Present

Summary:

1. The Primary Irritation Index= --

Toxicity Category: IV

3. Classification: Acceptable

Deviations From 81-5: None

Results: No irritation was reported in any animal during the observation period.

DATA REVIEW FOR SKIN SENSITIZATION TESTING (81-6)

Reviewer: M. Perry

Report Date:3/16/92

Report No.:8672-92

Product Manager: 13 MRID No.: 428890-05

Testing Laboratory: Stillmeadow

Author(s): J. Kuhn Species: Guinea pig

Weight: 280-370 g Source: Harlan SD

Test Material: Deltamethrin 4% Collar (reduced)

Positive Control Material: DNCB

Quality Assurance (40 CFR 160.12): Present

Method: Buehler

Summary:

 According to the study results, this Product is not a dermal sensitizer.

2. Classification: Acceptable

Deviation From 81-6: See recommendations

Results: No irritancy response was reported in the test or naive control animals at challenge.

ACUTE TOX ONE-LINER

1. PC CODE: 097805

2. CURRENT DATE: 5/12/95

3. TEST MATERIAL: Deltamethrin 4%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox.	Core Grade
81-1, Rat, Still- eadow, 8668-92, 3/11/92	428890-01	LD50 = 3920 mg/kg	III	· A
81-2, Rabbit, Still- meadow, 8669-92, 2/21/92	428890-02	LD50 2020 mg/kg	III	A
81-4, Rabbit, Still- meadow, 8670-92, 2/12/92	428890-03	Irritation cleared by 72 hrs.	III	A
81-5, Rabbit, Still- meadow, 8671-92, 2/11/92	428890-04	No irritation reported	IV	A
81-6, Guinea pig, Stillmeadow, 8672-92, 3/16/92	428890-05	Non-sensitizer		A

Core Grade Key:

A' = Acceptable

S = Supplementary

U = Unacceptable

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (81-4)

Reviewer: M. Perry

Report Date: 2/12/92

Report No.:8670-92

Product Manager:13 MRID No.:428890-03

Testing Laboratory: Stillmeadow

Author(s): J. Kuhn Species: Rabbit

Sex: 3 female, 3 male

Weight: --

Source: Ray Nichols

Dosage: 50,4 mg

Test Material: Deltamethrin 4% Collar (reduced)

Quality Assurance (40 CFR 160.12): Present

Summary:

1. Toxicity Category: III

2. Classification: Acceptable

Deviations From 81-4: None

Results: All "positive" scores cleared between 24 and 72 hours post dosing.

DELTAMETHRIN 3% COLLAR

FLEA & TICK COLLAR FOR DOGS

			/	GUARANTEED WATER PROOF
			1	KILLS FLEAS FOR 6 MONTHS
			1	KILLS TICKS FOR 4 MONTHS
		×	V	NEW MOLECULE - FIRST COLLAR FORMULATED WITH PYRETHROID
			1	ODORLESS
13	-		1	FITS DOGS WITH NECKS UP TO 21"
		100	1	GUARANTEED OR YOUR MONEY BACK
			1	ONE OF THE LONGEST LASTING FLEA
				& TICK KILLERS AVAILABLE FOR USE ON DOGS
			1	WETTING WILL NOT IMPAIR COLLARS EFFECTIVENESS
			1	MAY BE WORN WITH REGULAR COLLAR
			1	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENTS:	14	BY WEIGHT
Deltamethrin		3.00%
Inert Ingredients		97,00%
		100.00%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar NET WT. 1.1 oz

EPA REG. NO. 432-

EPA EST. NO.

CODE

Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvale, NJ 07645

DELTAMETHRIN 3% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 6 Month Flea Killer GUARANTEED 4 Month Tick Killer

Deltamethrin 3% Collar provides full season, 6 month flea killing power (and 4 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Deltamethrin 3% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 3% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 3% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 4 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 3% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

REG. NO: 00432-TTO Submission: 8452561

FILE SYMBOL: D196505

PRODUCT CHEMISTRY REVIEW FOR END USE PRODUCTS

PRODUCT NAME: Deltamethrin 4% Collar Company: Roussel Uclaf Corp.

TO: 13 George LaRocca/John Hebert

FROM: Shyam B. Mathur, Chemist Shuetur 12/29/93

THRU: Harold Podall, Section Head 11 Podell 12/29/9>

EMICAL: 097805 Deltamethrin

MRID NOS. Series 61(428935-01), Series 62(428935-02),

Beries 63 (428935-03)

Food Use () Non Food Use (X)

Inerts cleared: c () d () e () yes (X) no ()

Inerts List 1 () Other ()

NOTE: Inerts

are not cleared. See ATTACHMENT-3:

Please provide the requested information for the following checked items:

- [] Submit the specific chemistry data for your product.
- [] If submitted earlier, provide MRID Number(s).
- 2. [] Your product is not sufficiently similar to the product you referenced.
- 3. In reference to the Confidential Statement of Formula (CSF), please provide the following information of your product:
 - [] a) pH of a specified water dilution.
 - [] b) Density

- [] c) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate.
- [] d) The upper and lower certified limits of the individually added inerts.
- 4. Based on the current CSF (dated), your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so that the information agrees.
- 5. Provide the chemical identify of all components, the percentage composition, CAS Registry Numbers, and Material Safety Data Sheet (two copies) for the following compounds:
- 6. In the proposed labeling, provide the following information:
 - [] a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with [] PR Notice 84-1 for non-aerosol containers for houses and institutional uses of [] PR Notice 83-3 for all other uses.
 - [] b) Add the heading to the label per 40CFR§172-6(a)1.
 - [] c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as extremely Flammable (because your product contains flammable propellents). 40CFR§156.10(i)2(ix).

[] d) If the solvent has insecticidal activity provide the EPA Registration Number, if does not it should be removed from the active ingredient statement and added to the total percentage of the inert ingredients.

[] e) Add a footnote to the inert ingredients indicating: Contains petroleum distillates, xylene or xylene-range aromatic solvent.

 f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the physical or Chemical Hazards heading;

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

- [X] g) The terms active ingredient(s) and inert ingredients should be in the same type size, be aligned to the same margin and be equally prominent.
- 7. In reference to the product specific data requirements, provide the following information:
 - [] a) Statement of Composition: A complete description of the manufacturing formulation process. Describe equipment used, mixing time, temperature, pressure, etc. The Registrant described the full formulation procedure for this product; the process, the quantities and the order of addition is described in <u>Attachment-1</u>. (MRID No. 428935-01)

- [] b) Discussion of Formation of Unintentional Ingredients: The Registrant provided following information on this topic[MRID No.428935-01]: No unintentional inert ingredients are introduced in the blending or the filling processes. No unintentional inert ingredients are introduced by the market containers or by storage in them.
- [] c) Certification of Limits: Upper and lower limits or each active and individually added inert component. The Registrant submitted a CSF (dated 08/11/93) for Basic formulation of the product.
- [] d) Analytical Method: Provide the methods used to analyze for the active ingredients or a full reference for a published method or MRID Number(s). The Registrant submitted data on Series 62 under MRID No. 428935-02). See <u>Attachment-2</u>.

Series 63: MRID No. 428935-03

- [] e) Color: In common terms: White [SOP C-30]
- [] f) Physical State: Solid [SOP C-31]
- [] g) Odor: Odorless [SOP C-33]
- [] h) Density/Sp. Gravity: 72 lbs/cubic foot to 88 lbs/cubic foot [SOP C-35]
- [] i) pH: Not Applicable. The product is not dispersible in water.
- [] j) Oxidizing or Reducing Action: This product does not have the potential to act as a strong oxidizing or reducing agent.
- [] k) Explodability: This product possesses no explosive potential.
- [] 1) Viscosity: Not Applicable, the product is a solid.
- [] m) Miscibility: Not applicable as the product is not emulsifiable and is not intended to be diluted with both water and petroleum distillate.
- [X] n) Corrosion Characteristics: The Registrant did not provide any data on this topic.
- [] o) Dielectric Breakdown Voltage: NA as the product is not intended to be used around electrical equipment.

Product ingredient source information may be entitled to confidential treatment

-5-

- [X] p) Storage Stability: The Registrant did not submit any data on this topic.
 - [X] q) Flammability: NA. The product is solid. NOTE: This needs further explanation
- 8. [] The following is the regulatory status of the inert ingredients under 40CFR 180.1001 for the exemption of the requirement of a tolerance.
- 9. Other

Note to PM: Inter-office

Please notify the Registrant :

-). To correct the label as described in 6(g)[40CFR§156.10(g)]
- (2). To submit data on Storage stability(7p) and corrosion characteristics (7n).
- (3). To ask the Registrant whether the Flammability test was done with this product or not? The product being solid does not mean that it can not be Flammable.
- (4). To use same units for temperature (C or F) during describing the formulation process (Series 61-2). Request them to provide information on it, mixed units were used when the process is described (MRID No. 428935-01).
- (5). To correct the CAS No. of the AI Deltamethrin in the CSF submitted 8/11/93.

(6).

(7).

SUMMARY ATTACHED

TABLE 1: SUMMARY OF PRODUCT CHEMISTRY DATA REQUIREMENTS

GLR #	TITLES	
Series 167)	61-Product Identity and Composition (40CFR158.155, 160, 162, 165	. &
61-1	Product Identity & Disclosure of Ingredients	A
61-2	Description of Starting Materials & Manufacturing Process	A
61-3	Discussion of Formation of Impurities	A
	62-Analysis and Certification of Product Ingredients (40CFR158.1	.70,
62-1	Preliminary Analysis of Product Samples	NA
62-2	Certification of Ingredient Limits	A
62-3	Analytical Methods to Verify Certified Limits	A
Seri	ies 63-Physical and Chemical Characteristics (40CFR158.190)	
63-2	Color	A
63-3	Physical State	A
63-4	Odor	A
63-5	Melting Point	NA
3-6	Boiling Point	NA
63-7	Density, Bulk Density, or Specific Gravity	A
63-8	Solubility	NA
63-9	Vapor Pressure	NA
63-10	Dissociation Constant	NA
63-11	Octanol/Water Partition Coefficient	NA
63-12	рн	A
63-13	Stability	NA

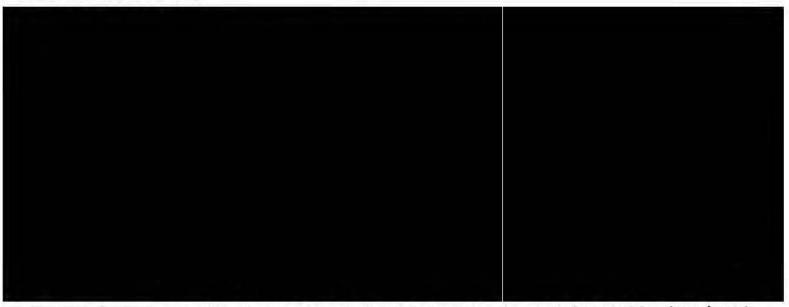
63-14	Oxidizing Or Reducing Action		A
63-15	Flammability		A(?)
63-16	Explodability		A
63-17	Storage stability		DG
63-18	Viscosity		NA
63-19	Miscibility		NA
63-20	Corrosion Characteristics		DG
-21	Dielectric Breakdown Voltage		NA
A	- Acceptable	Reviewer	
W	- Waived		
N	A - Not Applicable	Section Head	-
	G - Data Gap (?) - Acceptable with	Dates	

Confidential Statement of Formula may be entitled to confidential treatment

ATTACHMENT-1

DP BARCODE D196505 SUBMISSION S452561 REG. No. 432-TTO CHEMICAL 097805 Deltamethrin PRODUCT Deltamethrin 4% Collar COMPANY Roussel Uclaf Corporation.

61-1. Product Identity & Disclosure of Ingredients MRID No. 428935-01)



The Registrant submitted a CSF(Dated 8-11-93) which contains following inert ingredients not cleared by the agency:

	يتجمعه

ATTACHMENT-1 Contd....

DP BARCODE D196505 SUBMISSION S452561 REG. No. 432-TTO CHEMICAL 097805 Deltamethrin PRODUCT Deltamethrin 4% Collar COMPANY Roussel Uclaf Corporation.

61-2. Description of Beginning Material & Manufacturing Process (MRID No. 428935-01)



Manufacturing Process:

ATTACHMENT-2

<u>DP BARCODE</u> D196505 <u>SUBMISSION</u> S452561 <u>REG. No.</u> 432-TTO <u>CHEMICAL</u> 097805 Deltamethrin <u>PRODUCT</u> Deltamethrin 4% Collar <u>COMPANY</u> Roussel Uclaf Corporation.

Series 62. (MRID No. 428935-02)

62-1. Preliminary Analysis This product is not produced by an integrated formulation system, therefore, preliminary analysis is not required [40CFR§158.170].

62-2. Certification of Ingredient Limits

See the CSF given in Series 61-1.

62-3. Analytical method to verify certified limits:

Determination of Deltamethrin in collars:

the amount of the AI in the collar is determined by using reversed phase HPLC system. A portion of the collar is sliced into very thin crossections, then extracted(using a Ultrasonic bath) with acidified acetonitrile. The solution was then filtered and injected into stabilized HPLC system. Results are quantified using peak area measurements with an external standard.

ruitable liquid chromatograph equipped with a UV detector and electronic egrator was used under isocratic conditions:

Column: Supelco LC-18, 25 cm length, 2.1 mm ID, 5 micron particle size.

Detector: 254 nm (UV wavelength)

Mobile Phase: 80% Mobile phase A[mix 99.8% acetonitrile and 0.2% glacial acetic acid and filter through 0.22 μ Nylon 66 filter and degas]

20% Mobile phase B[mix 99.8% deionized wtaer and 0.2% glacial acetic acid and filter through 0.22 μ Nylon 66 filter and degas].

Flow Rate: 0.35 ml/ min.

Chart speed: 0.5 cm/min.

Run time: 20 min.

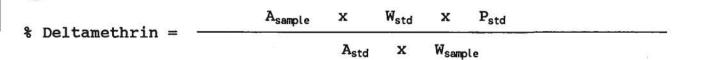
Sample loop volume: 5 μ l

ATTACHMENT-2 Contd....

<u>DP BARCODE</u> D196505 <u>SUBMISSION</u> S452561 <u>REG. No.</u> 432-TTO <u>CHEMICAL</u> 097805 Deltamethrin <u>PRODUCT</u> Deltamethrin 4% Collar <u>COMPANY</u> Roussel Uclaf Corporation.

Series 62. (MRID No. 428935-02)

Calculations:



A_{sample} = average peak area of deltamethrin in sample chromatogram

A_{std} = average peak area of deltamethrin in reference standard chromatogram

 W_{std} = weight of deltamethrin standard

 W_{sample} = weight of collar sample

F_{std} = % purity of deltamethrin standard.

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM*

ATTACHMENT 3

cr#: 93-0518

	P		12 410 70 1111		DECT		120.10-
TEL:()30			B. MATHUR	ROO		IL CODE: H	
IEL.: (8.8318	UMG.: PCK	(DIV_/BR_/SEG.)	, ROO	WLWA	L CODE_17	1303 0
CSF ATTACH	IED:		ļa.				
EYES	If CSF is	attached con	plete Item A and	the chemical r	ame in Item	B.	
O NO			complete Items A				
A. INFORMA	TION REQ	UIRED:	*				
Check Applica							
			emption Status Fo		er# Ingredien	t(s)	
			Inert Ingredient ((s)			
		Active Ingredi	ent(s)				
	e PCC for l			2			
			ptable for Use in F	Formulation			
U Other	(Describe):						_
B. INGREDIE	ENT INFOR	MATION:					
					Î		
C. PESTICID	E PRODUC	T INFORMA	TION:				
	THE COLUMN TO THE LOCAL		2.0.70				
	THE COLUMN TO THE LOCAL		TION:	e: Deltam	etarry 4	1% collar	
EPA Reg. No.	/File Symbo	ol: <u>432-T</u> T	2.0.70	e: <u>Deltam</u>	e)-h-ry	1% collar icide: □ YES	₩ NO
	/File Symbo	ol: 432-TT	p Product Name	F	e)-h-ry	1% <u>colla</u> vicide: □ YES	NO NO
EPA Reg. No. Registrant: 12	/File Symbo	ol: 432-TT	p Product Name	F	el-brig	1% collar ficide: ☐ YES	NO NO
EPA Reg. No. Registrant: 12	/File Symbo	ol: 432-TT	p Product Name	F	el-arry Cood-Use Pest	1°/。 collar ticide: □ YES	NO NO
EPA Reg. No. Registrant: Registrant: Represent in Fo	/File Symbo cousse / (rmulation (ol: 432-TT Uclat com For Fragrance	p Product Name	F	el-arry load-Use Pesi	1% collay	NO NO
EPA Reg. No. Registrant: <u>R</u>	/File Symbo cousse / (rmulation (ol: 432-TT Uclat com For Fragrance	p Product Name	F	e)-hriq Tood-Use Pest	1% collar ficide: □ YES	NO
EPA Reg. No. Registrant: @ Percent in Fo	/File Symbo	ol: 432-TT Uclat com For Fragrance	Product Name	ii	ood-Use Pesi	ticide: YES	NO
EPA Reg. No. Registrant: Registrant: Registrant: Registrant: Registrant: Registrant No. Registra	/File Symbo	ol: 432-TT Uclat com For Fragrance	Product Name (Dyes only):	F	ood-Use Pesi	ticide: YES	M NO
EPA Reg. No. Registrant: Registrant: Registrant: Registrant: Registrant: Registrant: Registrant No. Registrant	/File Symbo	ol: 432-TT Uclat com For Fragrance	ProductName possible possible possible lingredi PCC:	ient No. 2:	ood-Use Pesi	1% collar ficide: ☐ YES	NO NO
EPA Reg. No. Registrant: Registrant: Registrant: Registrant: Registrant: Registrant: Registrant No. Registrant: Registrant No. Registrant: Registrant No. Registrant: Registrant No. Registrant No. Registrant No. Registrant	/File Symbologies / (crusse / (cruss	ol: 432-TT Jelat com For Fragrance	ProductName posture e/Dyes only): Ingredi PCC: TOL 5	ient No. 2:	ood-Use Pesi	ticide: YES	NO NO
EPA Reg. No. Registrant: Registrant: Registrant: Registrant: Registrant No. Registrant No. Registrant No. Registrant No. Registratus: Registrant No. Registr	/File Symbologies / (crosse / (crosse / (crosse / (crosse / crosse	ol: 432-TT Jelat com For Fragrance D:	Ingredi PCC: TOL. S	ient No. 2: STATUS: R INF.:	ood-Use Pesi	ticide: YES	NO NO
EPA Reg. No. Registrant: Registrant: Registrant: Registrant: Registrant: Registrant No. Co. Co. Co. Co. Co. Co. Co. Co. Co. C	/File Symbologies Consister Consister	ol: 432-TT Jolat com For Fragrance D: Cific Comp	Ingredict Name of the state of	ient No. 2: STATUS: R INF.:	ood-Use Pesi	ticide: YES	NO NO
EPA Reg. No. Registrant: @Percent in Fo	/File Symbologies Consister Consister	ol: 432-TT Jolat com For Fragrance D: Cific Comp	Ingredict Name of the state of	ient No. 2: STATUS: R INF.:	ood-Use Pesi	ticide: YES	NO NO
EPA Reg. No. Registrant: Registrant: Registrant: Registrant: Registrant: Registrant: Registrant No. Registrant	/File Symbologies Consister Consister	ol: 432-TT Jolat com For Fragrance D: Cific Comp	Ingredie of the formal of the	ient No. 2: STATUS: R INF.: Lant® lent No. 4:	ood-Use Pesi	ticide: YES	M NO
EPA Reg. No. Registrant: Represent in Formation Ingredient No. Co. DL. STATUS: IHER INF.: Mand Cast Ingredient No. Co. DL. STATUS: DL. STATUS: DL. STATUS: DL. STATUS: DL. STATUS: DL. STATUS: D. Registrant No. Registrant No. Co. DL. STATUS: D. Registrant No. Reg	/File Symbologies / (Principle Symbologies / (ol: 432-TT Jelat con For Fragrance D: Citic Comp the above diservel	Ingredict PCC: TOL 5 Ingredict PCC: TOL 5 Ingredict PCC: TOL 5 TOL 5 TOL 5 TOL 5	ient No. 2: STATUS: R INF: Lant ient No. 4: STATUS:	ood-Use Pesi	ticide: YES	NO
EPA Reg. No. Registrant: Registrant: Registrant: Registrant: Registrant: Registrant: Registrant No. Registrant	File Symbologies (Consisted Consisted Consiste	D: 432-TT Jelat con For Fragrance D: Citic Comp the above con while Com while Com	Ingredie PCC: TOL 5	ient No. 2: STATUS: R INF: Lant ient No. 4: STATUS: R INF::	New	ticide: YES	NO
EPA Reg. No. Registrant: Repercent in Formation Ingredient No. Co. DL. STATUS: THER INF.: Mand Co. Ingredient No. Co. DL. STATUS: THER INF.: No. Co. DL. STATUS: THER INF.: No. Co. DL. STATUS: THER INF.: No. Co. Co. Co. Co. Co. Co. Co. Co. Co. C	File Symbolousse (course (course (course (course course (course (course	D: 432-TT Jelat con For Fragrance D: Citic Comp the above con while Com while Com	Ingredict PCC: TOL S Uposition OTHE Uposition OTHE Uposition OTHE Uposition OTHE Uposition OTHE	ient No. 2: STATUS: R INF: Lant ient No. 4: STATUS: R INF::	New	ticide: YES	NO NO



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MAR 23 1995

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Roussel Uclaf, S.A.,
Division Sante Animale
c/o Mr. John J. Lauber
Hoechst-Roussel Agri-Vet Company
Route 202-2026, P.O. Box 2500, Bedm. 31
Somerville, NJ 088760-1258

Dear Mr. Lauber:

Subject: Transfer of Pending Pesticide Registrations From Company Number 432 to Company Number 68451

Pursuant to your request in your letter and transfer agreement of February 14, 1995, we have approved the transfer of the following pending registrations from AgrEvo Environmental Health, Inc., company number 432, to Roussel Uclaf, S.A., Division Sante Animale, company number 68451.

The effective date of these changes is the date of this

Pending Product Name	Old EPA File Symbol	New EPA File Symbol
Deltamethrin 4% Collar	432-TTO	68451-R
Deltamethrin 3% Collar	432-TTI	68451-E

The products listed above are pending registrations and therefore cannot be marketed until they have been registered.

The transferred pending registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

By copy of this letter we are informing MagrEvo Environmental Health, Inc. of these changes. If you have any questions about this transfer please call Daria Mills at (703) 305-7406.

Sincerely,

John Jamula Chief Information Resources Section

Information Services Branch

Program Management and Support Div. (7502C)

AgrEvo Environmental Health, Inc.



United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460

100	х	Registration
10	715	Registration Amendment Other
		Other

OPP Identifier Number

	Section I
Company/Product Number	EPA Product Manager 3. Proposed Classification
432-TTO	George LaRocca
4. Company/Product (Name)	PM# X None Restricte
Deltamethrin 4%-Collar	13
5. Name and Address of Applicant (Include ZIP Code)	6. Expedited Review. In accordance with FIFRA Section 3(c)(3
Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvale, NJ 07645 Check if this is a new address	(b)(i), my product is similar or identical in composition and labelin to: EPA Reg. No.
	Product Name
	Section II
Amendment - Explain below	Final printed labels in response to Agency letter dated
Resubmission in response to Agency letter dated	
-	"Me Too" Application.
Notification - Explain below.	Other - explain below.
Explanation: Use additional page(s) if necessary. (For s	section I and Section II.)
	Production of the Control of the Con

	Section III
1. Material This Product Will Be Packaged In:	Water Saluble Backgring 2 Type of Container
Child-Resistant Packaging Unit Packaging	Water Soluble Packaging 2. Type of Container
Child-Resistant Packaging Unit Packaging Yes* Yes	Yes Metal
Child-Resistant Packaging Yes* X No Unit Packaging Yes X No	Yes Metal Plastic Glass Paper
Child-Resistant Packaging Yes* X No If "Yes," No. 10	Yes X No Per II "Yes," No. per No. per Wetal Plastic Glass Paper Other (Specify)
Child-Resistant Packaging Yes* X No If "Yes," * Certification must be Unit Packaging Unit Packaging Yes X No If "Yes," Unit Package wgt.	Yes X No Per II "Yes," No. per No. per Wetal Plastic Glass Paper Other (Specify)
Child-Resistant Packaging Yes* X No If "Yes," No. 10 * Certification must be submitted.	Yes X No Per If "Yes," Package wgt. No. per Container
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. * Certification must be submitted. 3. Location of Net Contents Information 4. Size(Yes X No Per If "Yes," Package wgt. S) of Retail Container No. per Container X On Label Directions
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. * Certification must be submitted. 3. Location of Net Contents Information X Label Container 1.1 Manner In Which Label Is Affixed To Product X I	Yes X No Per If "Yes," Package wgt. S) of Retail Container Oz. (1 collar) Other (Specify) On Label On Labeling accompanying product Other (Specify) Other (Specify)
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. Certification must be submitted. Location of Net Contents Information X Label Container Container Location of Which Label Is Affixed To Product X X	Yes X No Per If "Yes," Package wgt. S) of Retail Container Oz. (1 collar) Lithograph Paper glued Metal Plastic Glass Paper Other (Specify) On Label On Labeling accompanying product
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. Certification must be submitted. B. Location of Net Contents Information X Label Container Container 1.1 Manner In Which Label Is Affixed To Product	Yes X No Per If "Yes," Package wgt. S) of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Metal Plastic Glass Paper Other (Specify) On Label On Labeling accompanying product Other (Specify)
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. Submitted. 3. Location of Net Contents Information X Label Container Manner In Which Label Is Affixed To Product X X 1. Contact Point (Complete items directly below for identification)	Yes X No Per If "Yes," Package wgt. So of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Section IV Metal Plastic Glass Paper Other (Specify) On Label Directions On Labeling accompanying product Section IV fication of individual to be contacted, if necessary, to process this application.)
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. * Certification must be submitted. 3. Location of Net Contents Information X Label Container	Yes X No Per ainer If "Yes," Package wgt. S) of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Section IV fication of individual to be contacted, if necessary, to process this application.) Title Metal Plastic Glass Paper Other (Specify) On Label Directions On Labeling accompanying product On Labeling accompanying product Telephone No. (Include Area Cod
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. Submitted. 3. Location of Net Contents Information X Label Container Manner In Which Label Is Affixed To Product X X 1. Contact Point (Complete items directly below for identification)	Yes X No Per If "Yes," Package wgt. So of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Section IV Metal Plastic Glass Paper Other (Specify) On Label Directions On Labeling accompanying product Section IV fication of individual to be contacted, if necessary, to process this application.)
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. * Certification must be submitted. 3. Location of Net Contents Information X Label Container Container 1.1 Manner In Which Label Is Affixed To Product X X 1. Contact Point (Complete items directly below for identification)	Yes X No Per II "Yes," No. per Container S) of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Section IV fication of individual to be contacted, if necessary, to process this application.) Title Registration Specialist Metal Plastic Glass Paper Other (Specify) Other (Other (Specify) Other (Specify) Other (Specify) Tother (Specify) Telephone No. (Include Area Cool Registration Specialist (201) 307-9700
Child-Resistant Packaging Yes* X No If "Yes," No. If "Yes," Unit Package wgt. Container Location of Net Contents Information Location of Net Contents Information Label Container Manner In Which Label Is Affixed To Product Manner In Which Label Is Affixed To Product Contact Point (Complete items directly below for identification Sharon M. Johnston Certification must be X No. If Yes," No. If Yes," No. If Yes, "Unit Package wgt. Container Location of Net Contents Information 4. Size(X Label Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If Yes, "Unit Package wgt. Container Container Container Container Container Container Information Container Information Container Information Information Container Information In	Yes X No Per II "Yes," No. per Container S) of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Section IV fication of individual to be contacted, if necessary, to process this application.) Title Registration Specialist Metal Plastic Glass Paper Other (Specify) Other (Other (Specify) Other (Specify) Other (Specify) Tother (Specify) Telephone No. (Include Area Cool Registration Specialist (201) 307-9700
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. Certification must be submitted. 3. Location of Net Contents Information X Label Container Container Container Container Container Container Container Container Johnston Certification must be with the statements I have made on this form and acknowledge that any knowingly false or misleading shoth under applicable law.	Yes X No Per If Yes, No. per Package wgt. So of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Section IV fication of individual to be contacted, if necessary, to process this application.) Title Registration Specialist Call 1 st. Telephone No. (Include Area Cool Registration Specialist Call 1 st. Telephone No. (Include Area Cool Registration Specialist Call 1 st. Call 2 st. Telephone No. (Include Area Cool Registration Specialist Call 307–9700 Catlon d all attachments thereto are true, accurate and complete. Stamped)
Child-Resistant Packaging Yes* X No If "Yes," No. If "Yes," Unit Package wgt. Container Submitted. Label Container Manner In Which Label Is Affixed To Product The Contact Point (Complete items directly below for identification Sharon M. Johnston Certification must be Submitted. 1. Contact Point (Complete items directly below for identification) Certification must be Submitted. A Size(X Label Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be Submitted items directly below for identification in the container of identification in the conta	Yes No Plastic Glass Paper Other (Specify) Other (Specify)
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. * Certification must be submitted. 3. Location of Net Contents Information X Label Container Container Manner In Which Label Is Affixed To Product X Is a Contact Point (Complete items directly below for identification Name Sharon M. Johnston Certification must be X No. If "Yes," Unit Package wgt. 4. Size(X Label Container 1. 1 Contact Point (Complete items directly below for identification) Name Sharon M. Johnston Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container Certification must be X No. If "Yes," Unit Package wgt. Container Certification must be X No. If "Yes," Unit Package wgt. Container Certification must be X No. If "Yes," Unit Package wgt. Container I	Metal Plastic Glass Paper Other (Specify) (s) of Retail Container (s) of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Section IV fication of individual to be contacted, if necessary, to process this application.) Title Registration Specialist (201) 307–9700 Registration of all attachments thereto are true, accurate and complete. statement may be punishable by fine or imprisonment or Metal Plastic Glass Paper Other (Specify) On Label Directions Ton Label On Labeling accompanying product Telephone No. (Include Area Cool Cool Cool Cool Cool Cool Cool Coo
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. * Certification must be submitted. 3. Location of Net Contents Information X Label Container Container Manner In Which Label Is Affixed To Product X Is a Contact Point (Complete items directly below for identification Name Sharon M. Johnston Certification must be X No. If "Yes," Unit Package wgt. 4. Size(X Label Container 1. 1 Contact Point (Complete items directly below for identification) Name Sharon M. Johnston Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container 1. 1 Contact Point (Complete items directly below for identification) Certification must be X No. If "Yes," Unit Package wgt. Container Certification must be X No. If "Yes," Unit Package wgt. Container Certification must be X No. If "Yes," Unit Package wgt. Container Certification must be X No. If "Yes," Unit Package wgt. Container I	Yes X No Per If Yes, No. per Package wgt. So of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Section IV fication of individual to be contacted, if necessary, to process this application.) Title Registration Specialist Call 1 st. Telephone No. (Include Area Cool Registration Specialist Call 1 st. Telephone No. (Include Area Cool Registration Specialist Call 1 st. Call 2 st. Telephone No. (Include Area Cool Registration Specialist Call 307–9700 Catlon d all attachments thereto are true, accurate and complete. Stamped)
Child-Resistant Packaging Yes* X No If "Yes," Unit Package wgt. Container S. Location of Net Contents Information X Label Container S. Manner in Which Label is Affixed To Product X X X 1. Contact Point (Complete items directly below for identification in the statements I have made on this form and acknowledge that any knowingly false or misleading shoth under applicable law.	Metal Plastic Glass Paper Other (Specify) (s) of Retail Container (s) of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled Section IV fication of individual to be contacted, if necessary, to process this application.) Title Registration Specialist

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:
1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];

2. Confidential Statement of Formula (EPA Form 8570-4);

3. Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling;

5. Three copies of any data submitted:

6. Authorization letter where applicable;

7. Matrices where applicable. Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5×11 inch file. Mockup labels significantly smaller than 8.5×11 inches should be mounted on 8.5×11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned
 to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Mumber.
- EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief
explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the
Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach
a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.

2. Type of Retail Container - Indicate type of container in which product will be marketed.

5. Location of Met Contents - Specify the net contents of all retail containers for your product. 4. Size(s) of Reset Container - Specify the net contents of all reteil containers for your product.

Location of Use Directions - Indicate the location of the use directions for your product.

6. Wahner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration action i.e. new products registration, resubmission, "me-too," reregistration, etc. 6. EPA Use Only.

® ≎ EP	United States Enviror Office of Pesticid Washingt Applicatio	e Programs (H750) on, DC 20460 on for Pestic	5Č) X	Registra Amendr Other	ation	201011
		Section I		aL.		
. Company/Product Number		2. E	PA Product Manage		3. P	roposed Classification
, Company/Product (Name	432-TT0	PM	George Lako	cca	y	None Restrict
		1.22			1	
	ethrin 4% Collar		13 Towns of Parallel	u la sessende		FIEDA Cartina DIAV
Roussel Uclaf 95 Chestnut R Montvale, NJ	Ridge Road	(b)(to:	(i), my product is s			FIFRA Section 3(c)(omposition and labeli
Check if this i	is a new address					
Onder it this i			duct Name			
		Section I I			-	
Amendment - Explain be	elow		Final printed lake Agency letter dat	ls in response t	0	
			- rigority lotter date			
Resubmission in respon	nse to Agency letter dated			4		
	nse to Agency letter dated		"Me Too" Applica	tion.		
Notification - Explain be		ection I and Section	Other - explain be		-	/
Notification - Explain be	elow. nal page(s) if necessary. (For se		Other - explain be		-	-/-
Notification - Explain be	elow. nal page(s) if necessary. (For se	ection I and Section	Other - explain be			72
Notification - Explain be xplanation: Use addition	nal page(s) if necessary. (For se	ection III	Other - explain be	olow.	Container	7
Notification - Explain be xplanation: Use addition Material This Product W hild-Resistant Packaging	elow. nal page(s) if necessary. (For se	ection III Water Solut	Other - explain be		Container Metal	
Notification - Explain be xplanation: Use addition Material This Product Whild-Resistant Packaging Yes*	slow. nal page(s) if necessary. (For se	Water Solut	Other - explain be	olow.	Metal Plastic	
Notification - Explain be xplanation: Use addition Material This Product Whild-Resistant Packaging Yes* No	Selow. Selow.	Water Solution Yes	Other - explain be	olow.	Metal Plastic Glass Paper	
Notification - Explain be xplanation: Use addition Material This Product W hild-Resistant Packaging Yes* No Certification must be	slow. nal page(s) if necessary. (For se	Water Solution Yes No If "Yes,"	Other - explain be	2. Type of C	Metal Plastic Glass	
Notification - Explain be explanation: Use addition Material This Product Whild-Resistant Packaging Yes* No Certification must be submitted.	Selow. Selow.	Water Solution Yes X No If "Yes," Package wg	Other - explain be	2. Type of C	Metal Plastic Glass Paper Other (S	pecify)
Notification - Explain be xplanation: Use addition Material This Product Whild-Resistant Packaging Yes* X No Certification must be submitted. Location of Net Contents I	Selow. Selow.	Water Solution Yes X No If "Yes," Package wg	Other - explain be n II.) Die Packaging No. per container	2. Type of C X Location of Lai	Metal Plastic Glass Paper Other (S	pecify)tions
Material This Product Whild-Resistant Packaging Yes* No Certification must be submitted. Location of Net Contents I	Selow. Selow.	Water Solution III Water Solution Yes No If "Yes," Package wg of Retail Contain oz. (1 coll ithograph	Other - explain be	2. Type of C X Location of Lai	Metal Plastic Glass Paper Other (S	pecify)
Material This Product Wild-Resistant Packaging Yes* No Certification must be submitted. Location of Net Contents I	Selow. Selow.	Water Solution III Water Solution Yes No If "Yes," Package wg of Retail Contain oz. (1 coll ithograph aper glued	Other - explain be n II.) Die Packaging No. per container	2. Type of C X Location of Lai	Metal Plastic Glass Paper Other (S	pecify)tions
Notification - Explain be explanation: Use addition Material This Product Whild-Resistant Packaging Yes* X No Certification must be submitted. Location of Net Contents I	Selow. Selow.	Water Solution III Water Solution Yes No If "Yes," Package wg of Retail Contain oz. (1 coll ithograph aper glued tenciled	Other - explain be	2. Type of C X Location of Lai	Metal Plastic Glass Paper Other (S	pecify)tions
Material This Product Whild-Resistant Packaging Yes* No Certification must be submitted. Location of Net Contents In Manner In Which Label Is	Selow. Selow.	Water Solution III Water Solution Yes If "Yes," Package wg of Retail Contain oz. (1 coll ithograph aper glued tenciled Section IV	Other - explain be of II.) Die Packaging No. per container er 5. ar) Other (2. Type of OX Location of Lat On Labelli	Metal Plastic Glass Paper Other (S	pecify)tions ipanying product
Material This Product Whild-Resistant Packaging Yes* No Certification must be submitted. Location of Net Contents I Label Co Manner In Which Label Is	Selow. Selow.	Water Solution III Water Solution Yes If "Yes," Package wg of Retail Contain oz. (1 coll ithograph aper glued tenciled Section IV	Other - explain be of II.) Die Packaging No. per container er 5. ar) Other (2. Type of C X Location of Lai X On Labeling Coessary, to price	Metal Plastic Glass Paper Other (S	pecify)tions ipanying product
Material This Product Whild-Resistant Packaging Yes* No Certification must be submitted, Location of Net Contents I	Selow. Selow.	Water Solution III Water Solution Yes X No If "Yes," Package wg of Retail Contain OZ. (1 coll ithograph aper glued tenciled Section IV cation of individual Title	Other - explain be of II.) Die Packaging No. per container er 5. ar) Other (2. Type of OX Location of Lat X On Labelli On Labelli	Metal Plastic Glass Paper Other (S pel Direct pag accomp	pecify)tions ipanying product

Sharon M. Johnston

4. Typed Name

EPA Form 8570-1 (Rev. 12-90) Previous editions are obsolete.

August 11, 1993

Registration Specaalist 5. Date

White - EPA File Copy (original)

Yellow - Applicant copy

150

Product ingredient source information may be entitled to confidential treatment

Formulator's Exemption Statement

Applicant's Name and Address: EPA File Symbol/Registration Number: 432- TTO

Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvale, NJ 07645 Product Name: Deltamethrin 4% Collar

Date of Confidential Statement of Formula: August 11, 1993

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the following active ingredient(s):

deltamethrin

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another product.
- (3) Indicate by checking (A) or (B) below which paragraph applies:

X

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

	1	Source
Active Ingredient	Product Name	Registration Number
deltamethrin		
Signature Sharen M.S.	Name and Title Sharon M. Johnston Registration Specialist	Date August 11, 1993

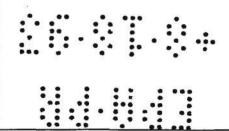
Certification with Respect to Citation of Data

							9475		
Applicant's Name and Address:			EPA File Symbol/Re	egistration Nu	mber: 432- T	TO	_		
	loussel Uclaf Corporation 5 Chestnut Ridge Road Iontvale, NJ 07645		Product Name: De	tamethrin 4%	Collar				
				Date of Application	August 1	1, 1993			
for the		uses, yo		00% repackaging of and t need to submit this fo					
1.	are incention of the composition	dicated, s of this quired to osition	this approduct be sub- and inte	oported by all data subrolication is supported by that is identical or subsmitted if this application nded uses under the ne appropriate boxes, in	y all data in the Agen tantially similar, and th sought the initial regis data requirements in	cy's files that lat is one of the tration of a pro- effect on the	concern the parent types of date oduct of identification date of appropriate control of the concern the concern the parent types.	roperties a that wo cal or sim roval of t	or uld ilar
2.	I certif	y that, fo	or each	study cited in support o	f this application for re	gistration that	t is an exclusiv	e use stu	dy,
,		am the o	original s	submitter*; or					
	_ II	have ob	tained th	ne written permission of	the original data sub	nitter to cite t	hat study*		
3.	I certif study:		or each	study cited in support	of this application for	registration th	nat is not an e	xclusive ι	ıse
	a.	M	I am t	he original data submitt	er*; or			77	Ø)
			I have	obtained the written pe	ermission of the origin	al data submi	tter to cite tha	t study*;	or
	b.		applic sectio (FIFR/ comp	notified in writing the cation and have offered n 3(c)(1)(D) and 3(c)(2)(A); and (b) Commencensation requirement of companies I have notified	to: (a) Pay compens (D) of the Federal Inside negotiations to de FIFRA and the amoun	ation for thos ecticide, Fung ermine which	e data in acco gicide and Rod n data are sul	rdance w lenticide / oject to 1	vith Act the
				contained in my prod	on the Pesticide Data uct (cite-all method or al Offer Statement bel	cite-all option			
				Those companies the method*)	at have submitted the	studies whi	ch I have cite	d (Select	ive
ā			ata Matri e-all met	x identifying these studi	es is attached. (Note:	a Data Matri	x is not require	ed under t	the
Signat	ure:		72	Name and Tit	le:	Date:		•	- 375
An	//	A.	He	Sharon M. Jo Registration S		10	8-11-5.	≩.	••
EnValue L	- - x - x			fer to Pay: I hereby regard to the approval					
Signat	ignature: Name and Tit				le:	Date:	•		
								152	· ·

Product Name: Deltamethrin 4% Collar		2. EPA Reg. No./File Symbol:		Formulator's Exemption Selected: YESXNO			4. Page <u>1</u> of <u>3</u>	
5. Applicant's Na	ame and Address:	6. Application fo	r Registration Dated:					
95 Chestr	Udaf Corporation nut Ridge Road , NJ 07645		11 / 93 DAY YR.	7. Name of Active In	gredient(s):	Deltamethrir	1	
8. DATA RE	QUIREMENTS	9. SOURCE	OF DATA SATISFYIN	G REQUIREMENT				10.
8a. Regulation Part 158/ Guideline No.	8b. Name of Test	9a. Submitted By Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	MRID Number, EPA Accession Number or Other EPA Identifying Number
§158.150	PRODUCT CHEMISTRY							
61-1	Chemical Identity	х	08-11-93	+				
61-2	Begin. Materials & Manufacturing Process	х	08-11-93					
61-3	Discussion of Formation of Impurities	х	08-11-93					
62-1	Preliminary Analysis						NA (formualtor's ex	kemption)
62-2	Certification of Ingredient Limits	х	08-11-93					
62-3	Analytical Method to Verify Certified Limits	х	08-11-93	•:				
63-2	Color	х	08-11-93					
63-3	Physical State	х	08-11-93					
63-4	Odor	х	08-11-93					
63-5	Melting Point		2				NA (formulator's ex	xemption)
63-6	Boiling Point						NA (formulator's ex	xemption)
63-7	Density Bulk Density or Specific Gravity	х	08-11-93					
63-8 Selubility							NA (formulator's ex	xemption)

1. Product Name	me: 2. EPA Reg. No./File Symbol: 3		3. Formulator's Exemption Selected:			4. Page 2 of 3		
	Deltamethrin 4% Collar		432-TTO		No		4. Page <u>2</u> of _	3
5 Applicant's N	ame and Address:	6 Application to	r Registration Dated:	YES <u>X</u>	NO			
95 Ches	Uclaf Corporation tnut Ridge Road e, NJ 07645	<u>08_/</u> MO.	11 / 93 DAY YR.	7. Name of Active Ingr	redient(s):	Deltamethrin		
8. DATA RE	QUIREMENTS	9. SOURCE	OF DATA SATISFYING	G REQUIREMENT				
O. DATA NE	CONTENTED TO	3. 300HOL	OF DATA GATIOF TIME	a regonement			8	10.
8a. Regulation Part 158/ Guideline No.	8b. Name of Test	9a. Submitted By Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	MRID Number, EPA Accession Number or Other EPA Identifying Number
§158.150	PRODUCT CHEMISTRY (Cont.)							
63-9	Vapor Pressure			VI.I.			NA (formulator's ex	emption)
63-10	Dissociation Constant						NA (formulator's ex	emption)
63-11	Octanol/Water Partition Coeffecient						NA (formulator's ex	remption)
63-12	рН						NA (not dispersible	with water)
63-13	Stability						NA (formulator's ex	kemption)
63-14	Oxidizing/Reducing Action	х	08-11-93					
63-15	Flammability						NA (does not conta liquids)	ain combustible
63-16	Explodability	х	08-11-93	10				
63-17	Storage Stability						NA (PR Notice 92-	5)
63-18	Viscosity						NA (not a liquid)	
63-19	Miscibility						NA (not an emulsif	iable concentrate)
63-20	Corrosion Characteristics				8	1	NA (not corrosive)	
63-2	Diefectric Breakdown Voltage					NA (not for use ard equipment)	ound electrical	
			2					# · ·

1. Product Name		V-7-	2. EPA Reg. No./File Symbol:		3. Formulator's Exemption Selected:			4. Page <u>3</u> of <u>3</u>	
	Deltamethrin 4% Collar		432-TTO	YES_>	NO		ŀ		
5. Applicant's N	ame and Address:	6. Application fo	r Registration Dated:			_			
95 Ches	Uclaf Corporation tnut Ridge Road e, NJ 07645	_ <u>08_/</u> MO.	11 / 93 DAY YR.	7. Name of Active Inc	gredient(s):	Deltamethrin			
8. DATA RE	EQUIREMENTS	9. SOURCE	OF DATA SATISFYIN	G REQUIREMENT				10.	
8a. Regulation Part 158/ Guideline No.	8b. Name of Test	9a. Submitted By Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	MRID Number, EPA Accession Number or Other EPA Identifying Number	
§158.340	TOXICOLOGY					(%-2			
81-1	Acute Oral LD ₅₀ - Rat	x	07-09-93						
81-2	Acute Dermal LD ₅₀ - Rat/Rabbit	х	07-09-93						
81-3	Acute Inhalation LC ₅₀ - Rat	х	07-09-93				Waiver Request		
81-4	Primary Eye Irritation - Rabbit	х	07-09-93						
81-5	Primary Dermal Irritation	х	07-09-93						
81-6	Dermal Sensitization	х	07-09-93						
81-7	1-7 Acute Delayed Neurotoxicity - Hen					V	NA (not an organo	phosphate)	
					200		34-11		
86-1	Domestic Animal Safety	x	07-09-93						



FLEA & TICK COLLAR FOR DOGS

✓	GUARANTEED WATER PROOF
√	KILLS FLEAS FOR 11 MONTHS
√	KILLS TICKS FOR 7 MONTHS
✓	NEW MOLECULE - FIRST COLLAR FORMULATED WITH
	PYRETHROID
✓	ODORLESS
✓	FITS DOGS WITH NECKS UP TO 21"
✓	GUARANTEED OR YOUR MONEY BACK
✓	ONE OF THE LONGEST LASTING FLEA
***	& TICK KILLERS AVAILABLE FOR USE
	ON DOGS
✓	WETTING WILL NOT IMPAIR COLLARS
	EFFECTIVENESS
✓	MAY BE WORN WITH REGULAR COLLAR
✓	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	4.00%
Inert Ingredients	96.00%
	100.00%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar NET WT. 1.1 oz

EPA REG. NO. 432-

EPA EST. NO.

CODE



FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CALITION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

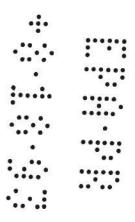
Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FTIS ALL-TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.



FLEA & TICK COLLAR FOR DOGS

GUARANTEED WATER PROOF
KILLS FLEAS FOR 11 MONTHS
KILLS TICKS FOR 7 MONTHS
NEW MOLECULE - FIRST COLLAR FORMULATED WITH
PYRETHROID
ODORLESS
FITS DOGS WITH NECKS UP TO 21"
GUARANTEED OR YOUR MONEY BACK
ONE OF THE LONGEST LASTING FLEA
& TICK KILLERS AVAILABLE FOR USE
ON DOGS
WETTING WILL NOT IMPAIR COLLARS
EFFECTIVENESS
MAY BE WORN WITH REGULAR COLLAR
PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	4.00%
Inert Ingredients	96.00%
	100.00%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar NET WT. 1.1 oz

EPA REG. NO. 432-

EPA EST. NO.

CODE



FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

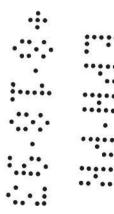
Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.



FLEA & TICK COLLAR FOR DGGS

√	GUARANTEED WATER PROOF
✓	KILLS FLEAS FOR 11 MONTHS
✓	KILLS TICKS FOR 7 MONTHS
✓	NEW MOLECULE - FIRST COLLAR FORMULATED WITH
	PYRETHROID
✓	ODORLESS
✓	FITS DOGS WITH NECKS UP TO 21"
✓	GUARANTEED OR YOUR MONEY BACK
✓	ONE OF THE LONGEST LASTING FLEA
	& TICK KILLERS AVAILABLE FOR USE
	ON DOGS
√	WETTING WILL NOT IMPAIR COLLARS
	EFFECTIVENESS
✓	MAY BE WORN WITH REGULAR COLLAR
✓	PATENTED INSECTICIDE RELEASE TECHNOLOGY
The second secon	

ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	4.00%
Inert Ingredients	96.00%
	100.00%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar **NET WT. 1.1 oz**

EPA REG. NO. 432-

EPA EST. NO.

CODE

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs)

the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

FLEA & TICK COLLAR FOR DOGS

✓	GUARANTEED WATER PROOF
✓	KILLS FLEAS FOR 11 MONTHS
. 🗸	KILLS TICKS FOR 7 MONTHS
✓	NEW MOLECULE - FIRST COLLAR FORMULATED WITH PYRETHROID
✓	ODORLESS
✓	FITS DOGS WITH NECKS UP TO 21"
✓	GUARANTEED OR YOUR MONEY BACK
✓	ONE OF THE LONGEST LASTING FLEA
	& TICK KILLERS AVAILABLE FOR USE
	ON DOGS
✓	WETTING WILL NOT IMPAIR COLLARS
	EFFECTIVENESS
✓	MAY BE WORN WITH REGULAR COLLAR
J	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	4.00%
Inert Ingredients	96.00%
V4.000.000 0.00 V2.000.00 U	100.00%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar NET WT. 1.1 oz

EPA REG. NO. 432-

EPA EST. NO.

CODE



FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

